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3	141	(((623/1.12) or (606/108)).CCLS.) AND kink$	USPAT; US-PGPUB	2004/02/02 12:06

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[45] **Date of Patent: Sep. 5, 2000**

[54] **STENT DELIVERY DEVICE**

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[73] Assignee: **Scimed Life Systems, Inc.**, Maple Grove, Minn.

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[51] **Int. Cl.**[7] **A61M 29/00**; A61M 5/00

[52] **U.S. Cl.** **606/108**; 604/264

[58] **Field of Search** 606/108, 198; 604/264, 96

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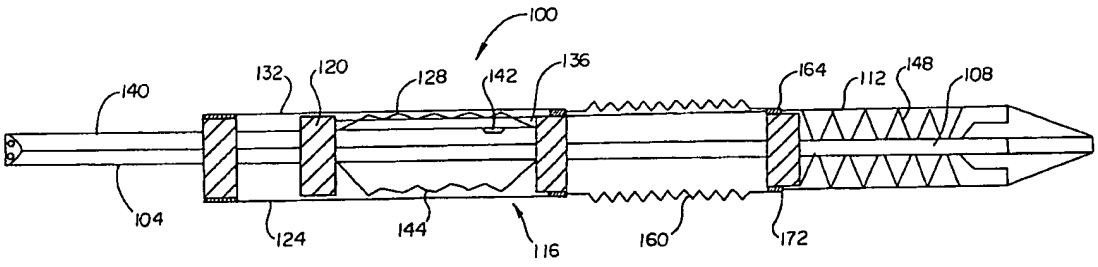
Primary Examiner—Paul J. Hirsch
Assistant Examiner—Michael B. Priddy
Attorney, Agent, or Firm—Vidas, Arrett & Steinkraus

[57] **ABSTRACT**

A stent delivery system having a hydraulically actuated retractable sheath is disclosed. A pressurizing fluid is either supplied by an inflation lumen to a portion of a piston housing or is withdrawn from a portion of a piston housing, thereby actuating a piston. As the piston moves, a retractable sheath which is connected to the piston moves as well causing the sheath to retract.

41 Claims, 4 Drawing Sheets



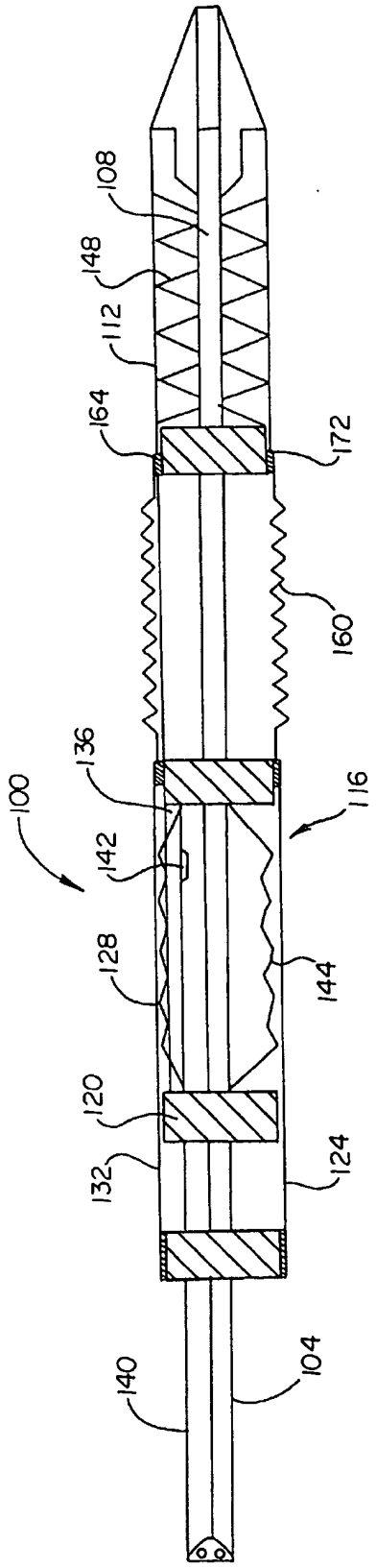

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Fig. 1

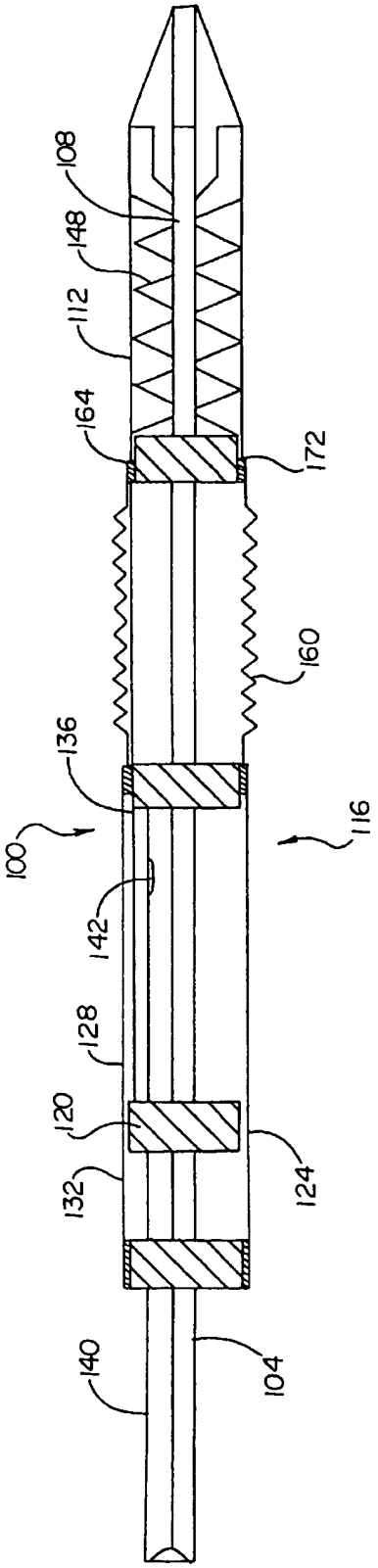

Fig. 2

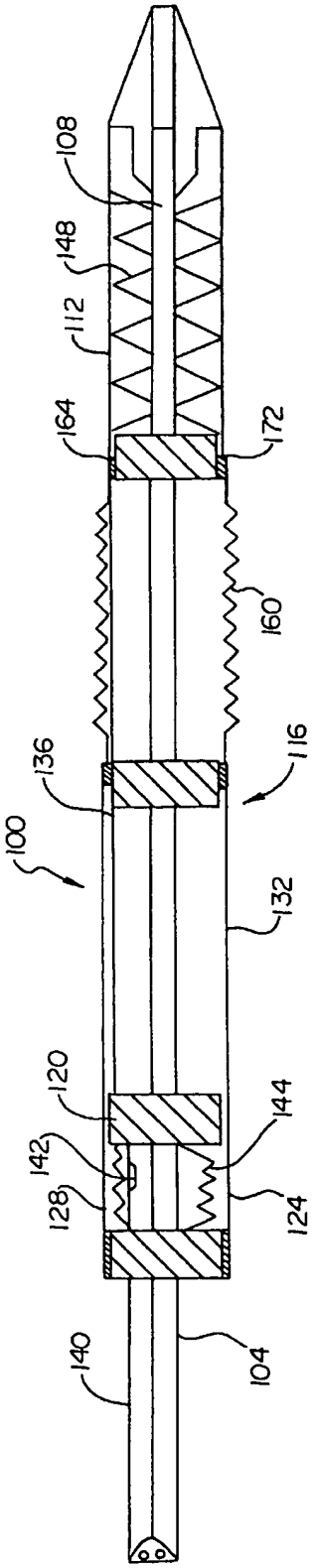
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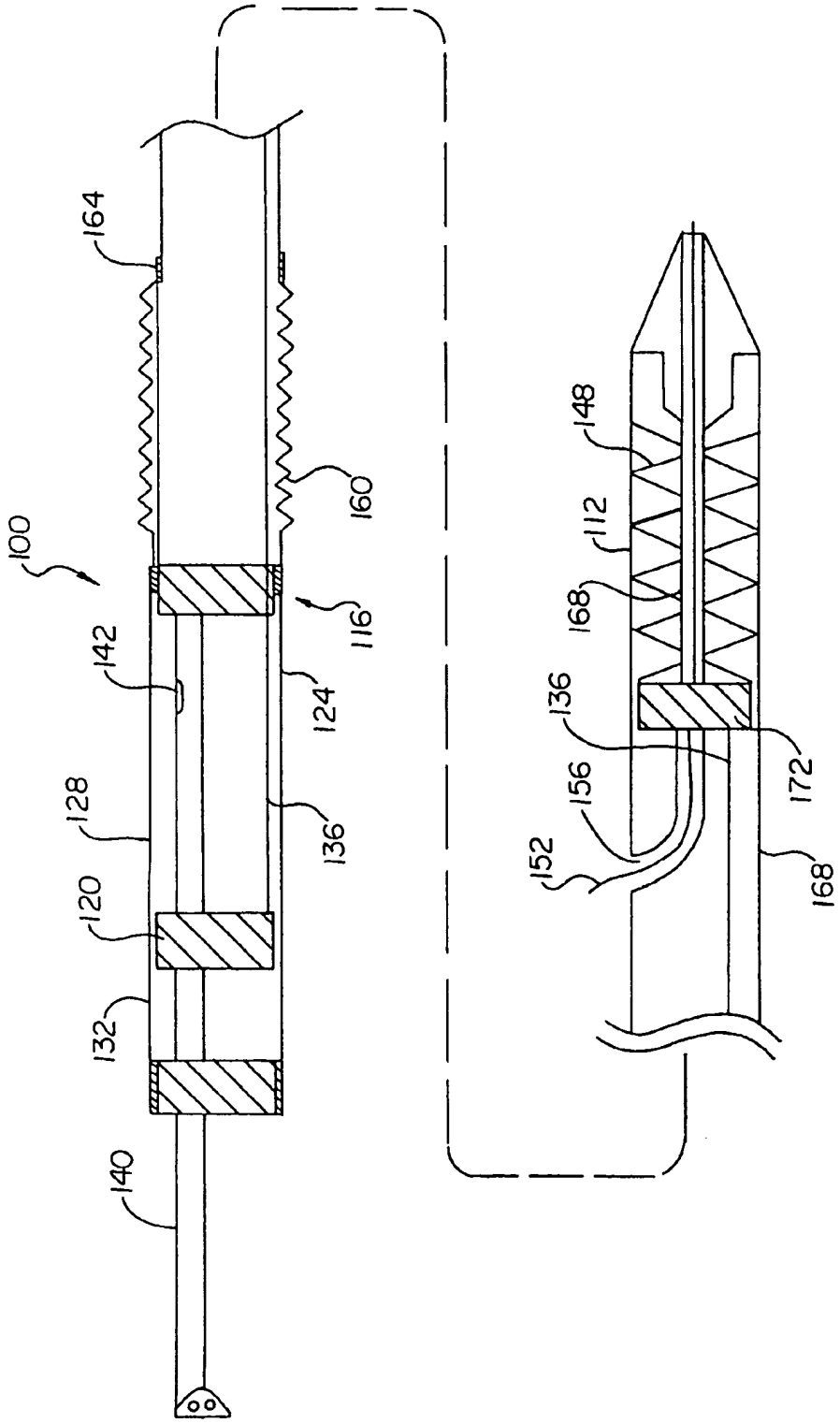
Fig. 3

Fig. 4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STENT DELIVERY DEVICE

BACKGROUND OF THE INVENTION

Stent delivery systems for deploying stents are a highly developed and well known field of medical technology. Stents have many well known uses and applications. A stent is a prosthesis which is generally tubular and which is expanded radially in a vessel or lumen to maintain its patency. Stents are widely used in body vessels, body canals, ducts or other body lumens.

The delivery systems for stents are generally comprised of catheters with the stent axially surrounding the distal end of the catheter. It is highly desirable to keep the profile of the catheter as small as possible. Therefore, self-expanding stents are generally confined in a reduced radius for delivery to the deployment site. Once the stent is deployed the catheter is removed, leaving the stent implanted at the desired location to keep the vessel walls from closing.

A variety of techniques have been developed for holding a self-expanding stent in its reduced configuration while moving the distal end of the catheter to the deployment site. For example, in U.S. Pat. No. 4,655,771 to Wallsten, gripping members at either end of the stent hold the stent in an axially-elongated position, which causes the stent to take a reduced radius delivery configuration.

Another common technique for maintaining the self-expanding stent in a reduced radius delivery configuration is using a sheath which surrounds the stent and compresses it around the catheter. This technique is disclosed in U.S. Pat. No. 5,071,407 to Termin and U.S. Pat. No. 5,064,435 to Porter, both of which use a silicon rubber sheath to compress the stent. A similar technique is disclosed in U.S. Pat. No. 5,026,377 to Burton and U.S. Pat. No 5,078,720 to Burton.

Unfortunately, deployment of stents, in particular, long and/or large stents, which are held in place by sheaths applying high frictional forces and compressive forces, can be quite difficult. Use of a manually operated pull-wire is not always adequate to retract a sheath. It is therefore desirable to provide a means for retracting sheaths which can apply sufficient force to overcome these high forces.

To that end, a catheter employing a piston-based hydraulic sheath retraction mechanism has been disclosed in co-pending, commonly assigned U.S. patent application Ser. No. 08/633,726, the entire contents of which are incorporated herein in its entirety by reference. Further to that end, the present invention provides a medical device delivery apparatus which employs a piston-based hydraulically operated retraction mechanism to apply sufficient force to the retractable sheath so as to withdraw the sheath from its initial position over the stent. The present invention also provides methods of delivering a medical device using a medical device delivery apparatus comprising a hydraulically operated piston.

SUMMARY OF THE INVENTION

In a general way, the present invention provides a mechanism for retracting a sheath to allow delivery of a medical device to a desired bodily location. Specifically, the medical device delivery apparatus comprises an elongate flexible catheter. At the distal end of the catheter is a medical device receiving region. A retractable sheath surrounds the medical device receiving region of the elongate catheter. Attached to the retractable sheath is a retraction device for retracting the retractable sheath. The retraction device comprises a piston housing having a first portion and a second portion therein.

A movable piston contained within the housing separates the first and second portions. The first portion has an inflatable element therein which is capable of applying a force to the piston so as to actuate the piston. Finally, a connecting member is connected at one end to a pull collar which is attached to the retractable sheath and at the other end to the piston.

In another embodiment, the medical device delivery apparatus is similar to that described above, however, the piston housing surrounds and is coaxial with a portion of the elongate flexible catheter. Further, the inflatable element is optional.

In yet another embodiment of the invention, the piston is characterized in that a transverse cross-section of the piston housing extends across a substantial portion of a transverse cross-section of the apparatus in the region of the piston.

In all of the above-described embodiments, the piston may pull or push the retractable sheath depending on whether the first portion of the housing is distal to the second portion of the housing or vice versa.

Moreover, in all of the above-described embodiments, the piston may be actuated by supplying an inflation fluid to the inflatable element or first housing portion. The inflation fluid for use in conjunction with the present invention is desirably biocompatible such as saline. Alternatively, the medical device delivery apparatus may be initially supplied with a fluid to the inflatable element or first housing portion and the piston then actuated by removing the fluid therefrom.

The invention is also directed to methods of delivering a medical device to a desired bodily location. Specifically, the invention entails providing any of the inventive medical device delivery apparatuses disclosed herein with a stent or other medical device surrounding the medical device receiving region. At least a portion of the apparatus is inserted in a bodily vessel and the stent or medical device advanced to a desired location. A source of fluid is provided and the fluid supplied under pressure to the inflatable element so as to actuate the piston and retract the sheath. The stent is deployed and the medical device delivery apparatus withdrawn from the bodily vessel.

The invention is also directed to methods of delivering a medical device to a desired bodily location using any of the inventive medical device delivery apparatuses disclosed herein by first supplying a fluid to the first piston housing and, after insertion of the apparatus in the bodily vessel and maneuvering the stent or medical device into position, removing at least some of the fluid from the first piston housing so as to actuate the piston and retract the sheath in order to deploy the stent.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a side elevational section showing a stent deployment device with a hydraulically actuated retraction mechanism including an inflatable element.

FIG. 2 is a side elevational section of another embodiment of the present invention showing a stent deployment device with a hydraulically actuated retraction mechanism without an inflatable element.

FIG. 3 is a side elevational section of another embodiment of the present invention showing a stent deployment device with a hydraulically actuated retraction mechanism.

FIG. 4 is a side elevational section of a rapid exchange embodiment of the present invention showing a stent deployment device with a hydraulically actuated retraction mechanism.

DETAILED DESCRIPTION OF THE INVENTION

The following detailed description should be read with reference to the drawings in which similar parts in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict exemplary embodiments and are not intended to limit the scope of the invention.

Examples of materials, dimensions, assemblies and manufacturing processes are provided for selected parts. All other parts employ that which is known to those skilled in the field of the invention. Those skilled in the art will recognize that many of the examples provided have suitable alternatives which may also be utilized.

A side elevational view of the distal end of an embodiment of the inventive medical device delivery apparatus is shown generally at **100** in FIG. 1. The device includes an elongate flexible catheter **104**. At the distal end of catheter shaft **104** is a medical device receiving region **108**. A retractable sheath **112** surrounds medical device mounting region **108** of catheter **104**. Retractable sheath **112** is operably connected to a retraction device, shown generally at **116**, for retracting retractable sheath **112**. Retraction device **116** includes a moveable piston **120** within a piston housing **124**, piston **120** separating first portion **128** of piston housing **124** from second portion **132** of piston housing **124**. First portion **128** of housing **124** is distal to second portion **132** of piston housing **124**. Piston **120** is proximal to retractable sheath **112**. A connecting member **136** also extends from piston **120** to pull collar **164** which is connected to retractable sheath **112** so that movement of the piston will result in an associated movement of the retractable sheath. Piston **120** is actuated by the supply of a fluid to first portion **128** of piston housing **124**. The fluid is supplied by inflation lumen **140** which extends to the proximal end of the device. Inflation lumen **140** is capable of fluid communication with the first portion of the piston housing via an opening **142** in the inflation lumen.

As shown in FIG. **1**, first portion **128** of piston housing **124** further contains an inflatable element **144** within. Inflatable element **144** is capable of fluid communication with inflation lumen **140**. As fluid is supplied to inflatable element **144**, inflatable element **144** expands so as to contact piston **120** and ultimately move piston **120** in a proximal direction. Because of the coupling between piston **120** and retractable sheath **112**, as piston **120** is displaced proximally by inflatable bladder **144**, retractable sheath **112** retracts from over medical device mounting region **108** in a proximal direction to expose medical device mounting region **108** or any medical device such as stent **148** mounted thereon. As operated in this mode, the retraction device functions as a pull device in that the retractable sheath is pulled from its unretracted position.

Retractable sheath **112** may further be returned to its unretracted position by withdrawing the fluid from inflatable element **144** and applying a suitable vacuum to inflatable element **144**. In this mode, retraction device **116** is acting as a push device, pushing sheath **112**.

Similarly, the device can be configured to retract sheath **112** in a distal direction by first supplying a fluid to inflatable element **144** so as to inflate inflatable element **144**. Retractable sheath **112** may then be retracted distally by withdrawing the fluid and pulling a vacuum on inflatable element **144**. The resulting distal movement of piston **120** is coupled with distal movement of retractable sheath **112**. Sheath **112** may similarly be returned to its unretracted position by supplying a fluid to inflatable element **144**.

Although a tight fit between the piston and the piston housing is desirable it is not absolutely necessary in the embodiment of FIG. **1** because the inflation fluid is contained within an inflatable element. Thus, regardless of whether the first and second piston housings are isolated from one another, the inflatable element can still actuate and move the piston on inflation or deflation.

Although an inflatable element is shown in FIG. **1**, its presence is optional. In the embodiment shown in FIG. **2**, the device differs from that shown in FIG. **1** only in the absence of an inflatable element as shown in FIG. **1**. In the device of FIG. **2**, the inflation fluid is supplied directly into the interior of first portion **128** of piston housing **124** via inflation lumen **140**. The fluid directly impinges on the piston and the fluid pressure actuates the piston.

Desirably, in such an embodiment, the first and second piston housings will be isolated from one another to prevent leakage of the inflation fluid from the first piston housing into the second piston housing. Such leakage would tend to equalize the pressure in the first and second piston housings, thereby preventing or reducing the ability of the piston to retract the sheath.

Leakage from one housing to the other housing may be reduced by using a piston that fits tightly in the piston housing, although not so tightly that it cannot be actuated. The piston also must form a tight fit with the catheter that runs therethrough. Alternatively, the piston may be slidably sealed to the piston housing. As such, the piston may be tethered all along its periphery to the piston housing via a thin, flexible sheet of material such as Teflon. The material should be of sufficient length to allow for desired range of motion of the piston. The piston may similarly be slidably sealed to the catheter that runs therethrough.

The use of slidably sealed components has been disclosed in co-pending commonly assigned U.S. patent application Ser. No. 08/722,834 filed Sep. 27, 1996, and a continuation-in-part application Ser. No. 09/071,484 filed May 1, 1998. The entire contents of both applications are hereby incorporated in their entirety by reference.

Use of a suitable lubricant, desirably biocompatible, on the piston, piston housing and catheter portion that traverses the piston may facilitate sliding of the piston within the housing.

As in the embodiment of FIG. **1**, the device may be used in both the push mode and in the pull mode.

In another embodiment of the invention, as shown in FIG. **3**, first portion **128** of piston housing **124** is proximal to second portion **132** of piston housing **124**. As in the previous embodiments, a fluid is supplied to first portion **128** of piston housing **124** so as to actuate piston **120**. The device so operates in push mode with sheath **112** being retracted by piston **120** pushing it.

Although inflatable element **144** is shown in FIG. **3**, the presence of the inflatable element is optional. Desirably, in the absence of the inflatable element, the first and second piston housing will be isolated from one another such as by slidably sealing piston **120** to piston housing **124** and to catheter shaft **104** as discussed above.

The device may also be employed with a fluid already supplied to first portion **128** of piston housing **124**. Piston **120** is then actuated by withdrawing the fluid and applying a vacuum to first portion of housing **124**. As such, the device operates in pull mode.

In any of the above embodiments, an additional guide wire (not shown) may extend through catheter **104** to the

distal end of the device. The inventive devices may also be made in fixed wire embodiments as are known in the art. In the case of the fixed-wire design, the guidewire is fixedly attached to the medical device delivery system. A fixed-wire delivery system is described in U.S. Pat. No. 5,702,364 to Euteneuer et al., incorporated herein in its entirety by reference, and may be suitably modified for use with the inventive medical device delivery system.

Although in the previous embodiments, the piston housing surrounds and is coaxial with a portion of the elongate flexible catheter, the invention also contemplates embodiments in which the piston does not surround any portion of the catheter. As such, the invention is also directed to a medical device delivery apparatus for implantation of a medical device in a vessel which comprises an elongate flexible catheter having proximal and distal ends. The catheter has a medical device receiving region at the distal end thereof. A retractable sheath surrounds at least a portion of the medical device receiving region. Operably connected to the retractable sheath is a retraction device for retracting the retractable sheath. The retraction device comprises a piston housing having a first and a second portion therein. The first and second portions are separated by a movable piston contained within the housing. The piston housing surrounds and is coaxial with a portion of the elongate flexible catheter. Connecting the piston and the retractable sheath via the pull collar is a connecting member. Fluid is supplied to the first piston housing via an inflation lumen. An inflatable bladder capable of fluid communication with the inflation lumen may optionally be present in the first piston housing.

An example of such a device is shown in FIG. **4**. The device of FIG. **4** is similar to the embodiment of FIG. **2**, modified for use as rapid exchange catheter. Desirably, guidewire **152** enters the device through guidewire port **156** in distal outer tube **168** located toward the distal end of the device. Distal outer tube **168** has a longitudinal groove therein to accommodate guidewire **152** on retraction of the sheath. Of course, in other configurations, the guidewire may enter the apparatus through a guidewire port located proximal of the piston. Regardless of the location of the guidewire port, the guidewire extends proximally to the proximal end of the device and beyond.

In the rapid-exchange embodiment of FIG. **4**, only a portion of the medical device delivery apparatus rides on the guidewire. Typically, the usable length of the medical device delivery system is approximately 135 cm. For a rapid-exchange medical device delivery system, the distance from where the guide wire accesses the inner tube to the distal tip will be approximately 5 cm to 45 cm. Other suitable features of a rapid exchange device may also be incorporated into the present apparatus, including those suitable features disclosed in U.S. Pat. No. 5,534,007 to St. Germain et al., incorporated herein in its entirety by reference.

Although the device as shown in FIG. **4** does not have an inflatable element, an inflatable element similar to that shown in FIG. **1** may be included in first portion **128** of housing **124**. Similarly, the device of FIG. **4** may be configured similarly to that shown in FIG. **3**, with the first portion of the piston housing proximal to the second portion of the housing. Again, an inflatable element is optionally present in such an embodiment.

The invention also contemplates a medical device delivery apparatus in which a transverse cross-section of the piston housing extends across a substantial portion of a transverse cross-section of the apparatus in the region of the piston. To that end, the medical device delivery apparatus comprises an elongate flexible catheter extending longitudinally and having proximal and distal ends. The catheter has a medical device receiving region at the distal end thereof. A retractable sheath surrounds at least a portion of the medical device receiving region of the elongate catheter. The retractable sheath may be retracted via a retraction device. The retraction device comprises a piston housing having a first and a second portion therein which are separated by a movable piston contained within the housing. A connecting member extends from a pull collar which is in contact or mechanical communication with the retractable sheath to the piston. The piston on actuation moves in a longitudinal direction. The apparatus is further characterized in that a transverse cross-section of the piston housing extends across a substantial portion of a transverse cross-section of the apparatus in the region of the piston. Several different embodiments incorporating this feature are shown in FIGS. **1–4**.

Although the inflatable element may be formed in a variety of different shapes, it is desirably accordion shaped and designed to expand in a longitudinal direction upon inflation so as to apply a force to the piston. Desirably, the inflatable element is bonded at one end to the inner tube and at the other end to the piston. Suitable materials for the inflatable element include polyolefin copolymer, polyester, polyethylene terephthalate, polyethylene, polyether block amide, polyamide, polyimide, nylon, latex and urethane as well as other suitable balloon materials as are known in the art.

Inflation fluid may be supplied to or removed from the first portion of the piston housing via an inflation lumen. The inflation lumen may be made of suitable materials as are known in the art including polyethylenes, polyimides and polyolefin copolymers. Although only one opening is shown in the inflation lumens in the figures, the inflation lumen may have additional openings therein. The hole may be a nick in the inflation large enough for inflation fluid to flow therethrough.

The second portion of the piston housing may be sealed or have one or more openings therein. The presence of one or more openings may help prevent the build-up of pressure in the second piston housing as the piston is actuated and the volume of the second piston housing decreased. Where the second piston housing is proximal to the first piston housing, the second piston housing may also be capable of fluid communication with a manifold at the proximal end of the catheter. To avoid the possibility of air bleeding from the second piston housing into the body where there are openings in the second piston housing, the second piston housing may be primed with a biocompatible fluid.

Each embodiment of the inventive apparatuses may be operated in one of two modes. In the first mode, as disclosed above, the piston is actuated by supply of a fluid to the first portion of the piston housing. In the second mode of operation, the piston is actuated by removal of a fluid from the first piston housing. As the fluid is removed and a vacuum drawn on the first piston housing, the piston moves from its initial position retracting the sheath. Desirably in this case, the opening in the inflation lumen will be at the opposite end of the first piston housing from the piston.

In all of the above embodiments, it should be noted that where a vacuum is applied to the piston housing, the vacuum cannot be so low as to damage the device.

The second mode of operation may also be carried out by securing the piston to the piston housing by an elastic or otherwise resilient joining member. The joining member

may be a spring placed behind the piston or a rubber bladder. While fluid is present in the first piston housing, the piston is displaced from an equilibrium position in which no force is exerted on the piston by the member. The restoring force of the joining member is offset by the fluid pressure against the piston. The joining member may either be under tension or compression depending on where the member is anchored to the piston housing. As the fluid is removed from the first piston housing, the elastic or resilient member acts like a spring and pulls or pushes the piston back to an equilibrium position in which no forces are exerted on it by the joining membrane.

In those embodiments in which the first portion of the piston housing is proximal to the second portion of the piston housing, the first portion of the piston housing may optionally extend to the proximal end of the device. In such case, a separate inflation lumen may not be necessary as the inflation fluid may be supplied directly through the manifold to the first portion of the piston housing and/or may be directly removed from the first portion of the piston housing.

The connector element may be a wire or a rod made of a suitable metal such as stainless steel or a polymeric material. Where the device is to be operated in push mode, the connector element should be relatively incompressible and buckle resistance under a compressive force. Where the device is to be operated in pull mode, the connecting member can be made of any suitable material having a tensile strength so that the connecting element does not deform or break under tension.

In a preferred embodiment of the invention, the inventive medical device delivery system further comprises an accordion-like collapsible sheath **160** between piston housing **124** and medical device mounting region **108**, as shown in FIGS. **1–4**. The proximal end of collapsible sheath **160** is attached, desirably adhesively bonded, to the distal end of piston housing **124**. Of course, other configurations are possible as well. For example, the apparatus may further comprise an outer tube in which at least a portion of catheter shaft **104** and piston/piston housing **124** are carried. In such case, the proximal end of collapsible sheath **160** may be fixedly attached to the distal end of such an outer tube. The distal end of collapsible sheath **160** is, in turn, attached, desirably adhesively bonded, to pull collar **164**. Additional information about the collapsible sheath made be found in U.S. Pat. No. 5,534,007 to St. Germain and Olson, incorporated herein in its entirety by reference.

The inventive medical device may be constructed such that the retractable sheath is withdrawn into an outer catheter as described in commonly assigned patent U.S. Pat. No. 5,772,669 and commonly assigned and copending U.S. application Ser. No. 09/071,484 both of which are hereby incorporated in their entirety by reference. The pull back means disclosed therein may be modified using the piston system as disclosed herein.

Pull collar **164** is a ring-shaped member of stainless steel or preferably of a radio-opaque material such as gold affixed to the distal end of collapsible sheath **160** by an appropriate adhesive such as a urethane. Pull collar **164** is also attached, desirably adhesively bonded, to retractable sheath **112** either directly (as shown in FIGS. **1–3**) or indirectly via a distal outer tube **168** as shown in FIG. **4**.

Optional distal outer tube may be made of suitable materials, such as polymeric materials, as are known in the art.

The medical device delivery apparatus disclosed herein, when configured for use with a stent, may further comprise one or more bumpers **172** as are known in the art.

Additionally, radio-opaque markers may be included in the apparatus to facilitate positioning the medical device in the body.

Optionally, the medical device delivery apparatus may further comprise a balloon. Desirably, the balloon will be mounted about the medical device receiving region of the catheter. Where stents and grafts are to be delivered, the balloon may be used to expand, assist in expansion or seat the stent or graft. Where a balloon is included, the apparatus must be further modified to have a balloon inflation lumen capable of fluid communication with the balloon. Further, a manifold which can accommodate the balloon inflation lumen must be used.

The inventive apparatuses may further comprise other standard components as are known to be used with catheters, including a manifold, as discussed above. Any suitable manifold which is capable of delivering a fluid to an inflation lumen may be used.

Generally, connections between the various polymer components may be made utilizing suitable medical grade adhesives or thermal bonds well known in the art. Connections between metallic components may be made, for example, by utilizing a solder, braze or weld.

The inventive medical device delivery apparatus may further comprise an outer stiffening shaft such as that disclosed in commonly assigned patents, U.S. Pat. No. 5,571,168 to Del Toro and U.S. Pat. No. 5,733,267 to Del Toro, both of which are incorporated herein in their entirety by reference.

The inventive medical device delivery apparatus, in all of its embodiments, may be used to deliver medical devices such as stents, vena cava filters and grafts. Other suitable medical devices may also be delivered.

The present invention is also directed to methods of delivering a medical device to a desired bodily location using the inventive apparatuses disclosed herein. More particularly, the method involves providing an inventive medical device delivery apparatus as disclosed above with a medical device received about the medical device receiving region. At least a portion of the apparatus is inserted in a bodily vessel distal end first. The distal of the apparatus and hence, the medical device, is advanced to a desired location. A fluid is then supplied under pressure to the first piston housing so as to actuate the piston and retract the sheath. The medical device is then deployed and the medical device delivery apparatus withdrawn from the bodily vessel. Desirably, the medical device delivered to the bodily location will be a stent, graft or vena cava filter. More desirably, the device will be a self-expanding, balloon expandable or balloon assisted expandable stent. Optionally, the retractable sheath may be closed again by removing the inflation fluid from the first piston housing and pulling a vacuum on the first piston housing or by a restorative spring-like force of a member connecting the piston to the piston housing. The apparatus may then be removed from the body.

In another embodiment, the apparatus is inserted as above. However, the first piston housing of the apparatus has a fluid therein. The piston is then actuated by removing the fluid therefrom and applying a vacuum to the piston housing. Alternatively, where the piston is attached to the piston housing by an elastic, resilient or otherwise spring-like member, the piston is initially displaced from its equilibrium position by the fluid present in the first piston housing. Upon removal of the fluid from the first piston housing, the piston will return to its equilibrium position via a spring-like restoration force exerted by the member. In either case, the

movement of the piston causes retraction of the sheath, allowing for deployment of the medical device such as a stent. Optionally, the sheath may be closed following deployment of the medical device by adding fluid back to the first piston housing. The apparatus may then be removed from the body.

Where the apparatus comprises a balloon, the inventive methods may further comprise the step of inflating the balloon so as to dilate a lesion, expand, assist in expanding or seat a medical device such as a stent.

For the purposes of this disclosure, the terms medical device receiving region and medical device mounting region as used herein are intended to describe a region of the catheter on which or about which a medical device is mounted. The device may be in physical contact with the region, as in the case of a stent crimped to the catheter. Alternatively, the medical device may surround at least a portion of the region, as in the case of certain self-expanding stents that are held in place by a sheath although they do not actually contact the catheter.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A medical device delivery apparatus for delivery of a medical device to a desired bodily location, the apparatus having a proximal and a distal end and comprising:
   - an elongate flexible catheter having proximal and distal ends, the catheter having a medical device receiving region at the distal end thereof;
   - a retractable sheath for surrounding the medical device receiving region of the elongate catheter;
   - a retraction device for retracting the retractable sheath, the retraction device comprising:
     - a piston housing having a first portion and a second portion therein, the first and second portions separated by a movable piston contained within the housing,
     - the first portion having an inflatable element therein, and
     - a connecting member, one end of which is in mechanical communication with the retractable sheath, the other end of the connecting member connected to the piston.

2. The medical device delivery apparatus of claim 1 further comprising a medical device surrounding the medical device receiving region of the flexible catheter.

3. The medical device delivery apparatus of claim 2 wherein the medical device is selected from the group consisting of stents, vena cava filters and grafts.

4. The medical device delivery apparatus of claim 3 wherein the first portion of the piston housing extends to the proximal end of the device.

5. The medical device delivery apparatus of claim 3 further comprising an inflation lumen capable of fluid communication with the inflatable element.

6. The medical device delivery apparatus of claim 3 wherein the first portion of the piston housing is proximal of the second portion of the piston housing.

7. The medical device delivery apparatus of claim 6 wherein the connecting member is relatively rigid.

8. The medical device delivery apparatus of claim 3 wherein the first portion of the piston housing is distal of the second portion of the piston housing.

9. The medical device delivery apparatus of claim 3 wherein the connecting member is a wire.

10. The medical device delivery apparatus of claim 3 wherein the second portion of the piston housing is sealed.

11. The medical device delivery apparatus of claim 3 wherein the second portion of the piston housing has pressure relief openings therein.

12. The medical device delivery apparatus of claim 3 wherein the second portion of the piston housing has a bio-compatible fluid therein.

13. The medical device delivery apparatus of claim 3 wherein the inflatable element is accordion shaped.

14. The medical device delivery apparatus of claim 3 wherein the apparatus is configured in a configuration selected from the group consisting of a rapid exchange configuration, an over-the-wire configuration and a fixed-wire configuration.

15. The medical device delivery apparatus of claim 3 wherein the piston housing surrounds and is coaxial with a portion of the elongate flexible catheter.

16. The medical device delivery apparatus of claim 3 wherein a transverse cross-section of the piston housing extends across a substantial portion of a transverse cross-section of the apparatus in the region of the piston.

17. The medical device delivery apparatus of claim 1 wherein the piston is actuated by supplying a fluid to the inflatable element.

18. The medical device delivery apparatus of claim 1 wherein the inflatable element contains an inflation fluid therein and the piston is actuated is by removing at least some of the fluid from the inflatable element.

19. A medical device delivery apparatus for implantation of a medical device in a vessel comprising:
   - an elongate flexible catheter having proximal and distal ends, the catheter having a medical device receiving region at the distal end thereof
   - a retractable sheath surrounding at least a portion of the medical device receiving region;
   - a retraction device for retracting the retractable sheath, the retraction device comprising:
     - a piston housing having a first and a second portion therein, the first and second portions separated by a movable piston contained within the housing, the piston housing surrounding and coaxial with a portion of the elongate flexible catheter, and
     - a connecting member, one end of which is in mechanical communication with the retractable sheath, the other end of the connecting member connected to the piston.

20. The medical device delivery apparatus of claim 19 further comprising a medical device surrounding the medical device receiving region of the flexible catheter near its distal end.

21. The medical device delivery apparatus of claim 20 wherein the medical device is selected from the group consisting of stents, vena cava filters and grafts.

22. The medical device delivery apparatus of claim 21 wherein the apparatus is configured in a configuration selected from the group consisting of a rapid exchange configuration, an over-the-wire configuration and a fixed-wire configuration.

23. The medical device delivery apparatus of claim 21 further comprising an inflation lumen capable of fluid communication with the first portion of the piston housing.

24. The medical device delivery apparatus of claim 23 further comprising an inflatable element within the first portion of the piston housing, the inflatable element capable of fluid communication with the inflation lumen.

25. The medical device delivery apparatus of claim 21 wherein the first portion of the piston housing is proximal of the second portion of the piston housing.

26. The medical device delivery apparatus of claim 25 wherein the first portion extends to the proximal end of the device.

27. The medical device delivery apparatus of claim 21 wherein the connecting member is relatively rigid.

28. The medical device delivery apparatus of claim 21 wherein the first portion of the piston housing is distal of the second portion of the piston housing.

29. The medical device delivery apparatus of claim 21 wherein the connecting member is a wire.

30. The medical device delivery apparatus of claim 21 wherein the second portion of the piston housing is sealed.

31. The medical device delivery apparatus of claim 21 wherein the second portion of the piston housing has pressure relief openings therein.

32. The medical device delivery apparatus of claim 21 wherein the second portion of the piston housing has a bio-compatible fluid therein.

33. The medical device delivery apparatus of claim 21 wherein the piston is slidably sealed to the catheter.

34. The medical device delivery apparatus of claim 19 wherein the piston is actuated by supplying a fluid to the first portion of the housing.

35. The medical device delivery apparatus of claim 19 wherein the first portion of the housing contains an inflation fluid therein and the piston is actuated is actuated by removing at least some of the fluid from the first portion of the housing.

36. A method for delivering a stent to a desired bodily location using the apparatus of claim 3 comprising the steps of:

providing a medical device delivery apparatus as in claim 3 wherein the medical device is a stent;

inserting at least a portion of the device in a bodily vessel;

advancing the stent to a desired location;

providing a source of fluid;

supplying the fluid under pressure to the inflatable element so as to actuate the piston and retract the sheath;

deploying the stent;

withdrawing the medical device delivery apparatus from the bodily vessel.

37. The method of claim 36 further comprising the step of priming the second portion of the piston housing.

38. A method for delivering a stent to a desired bodily location using the apparatus of claim 18 comprising the steps of:

providing a medical device delivery apparatus as in claim 18, the device further having a stent surrounding the medical device receiving region;

inserting at least a portion of the device in a bodily vessel;

advancing the stent to a desired location;

removing at least a portion of the fluid from the inflatable element so as to actuate the piston and retract the sheath;

deploying the stent;

withdrawing the medical device delivery apparatus from the bodily vessel.

39. A method for delivering a stent to a desired bodily location using the apparatus of claim 19 comprising the steps of:

providing a medical device delivery apparatus as in claim 19, the device further having a stent surrounding the medical device receiving region;

inserting at least a portion of the device in a bodily vessel;

advancing the stent to a desired location;

providing a source of fluid;

supplying the fluid under pressure to the inflatable element so as to actuate the piston and retract the sheath;

deploying the stent;

withdrawing the medical device delivery apparatus from the bodily vessel.

40. A method for delivering a stent to a desired bodily location using the apparatus of claim 35 comprising the steps of:

providing a medical device delivery apparatus as in claim 35, the device further having a stent surrounding the medical device receiving region;

inserting at least a portion of the device in a bodily vessel;

advancing the stent to a desired location;

providing a source of fluid;

removing at least a portion of the fluid from the inflatable element so as to actuate the piston and retract the sheath;

deploying the stent;

withdrawing the medical device delivery apparatus from the bodily vessel.

41. A method for delivering a medical device to a desired bodily location comprising the steps of:

providing a medical device delivery apparatus comprising:

a) an elongate flexible catheter having proximal and distal ends, a medical device receiving region at the distal end thereof, a medical device mounted on the medical device receiving region;

b) a retractable sheath for surrounding the medical device receiving region of the elongate catheter;

c) a retraction device for retracting the retractable sheath, the retraction device comprising:

i) a piston housing having a first portion and a second portion therein, the first and second portions separated by a movable piston contained within the housing, the first portion having a fluid therein; and

ii) a connecting member, one end of which is in mechanical communication with the retractable sheath, the other end of the connecting member connected to the piston;

inserting at least a portion of the apparatus in a bodily vessel;

advancing the medical device to a desired location;

removing at least a portion of the fluid from the first portion of the piston housing so as to actuate the piston and retract the sheath;

deploying the medical device;

withdrawing the medical device delivery apparatus from the bodily vessel.

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(54) STENT DELIVERY SYSTEM HAVING DELIVERY CATHETER MEMBER WITH A CLEAR TRANSITION ZONE

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(57) ABSTRACT

A catheter based stent placement system in which the catheter has a clear or translucent transition zone for visual inspection of the stent when placed in the catheter.

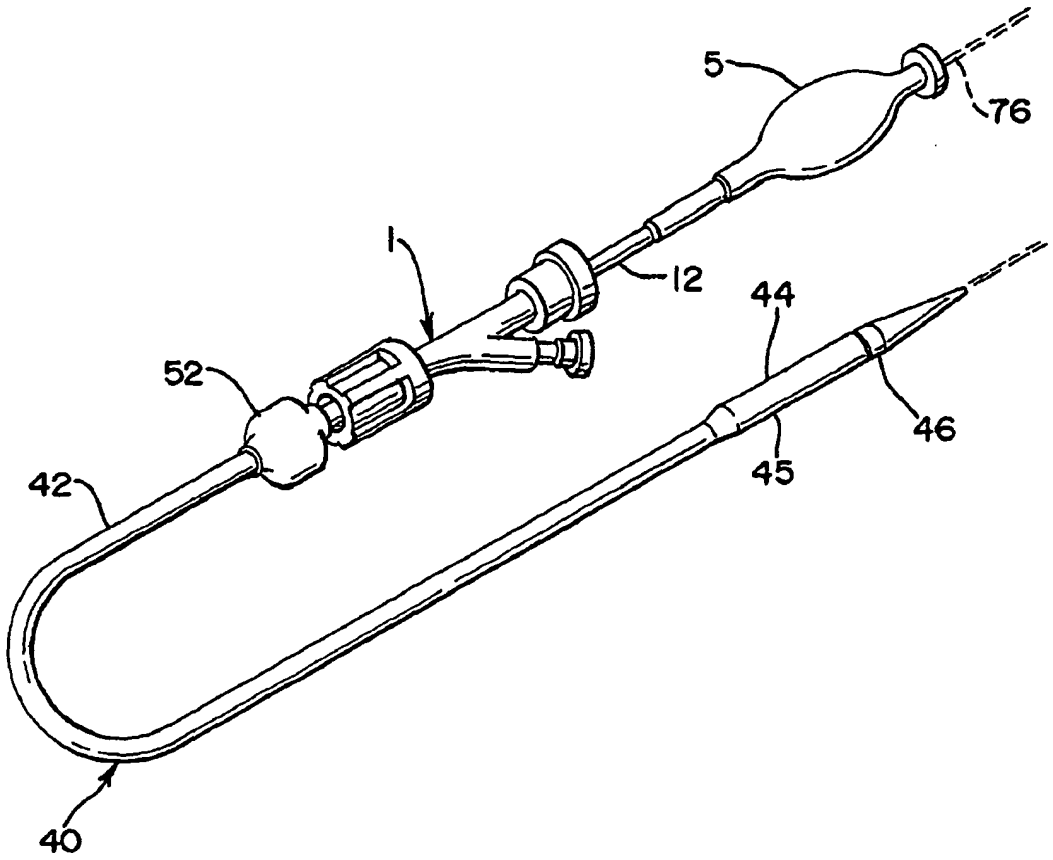


FIG.1

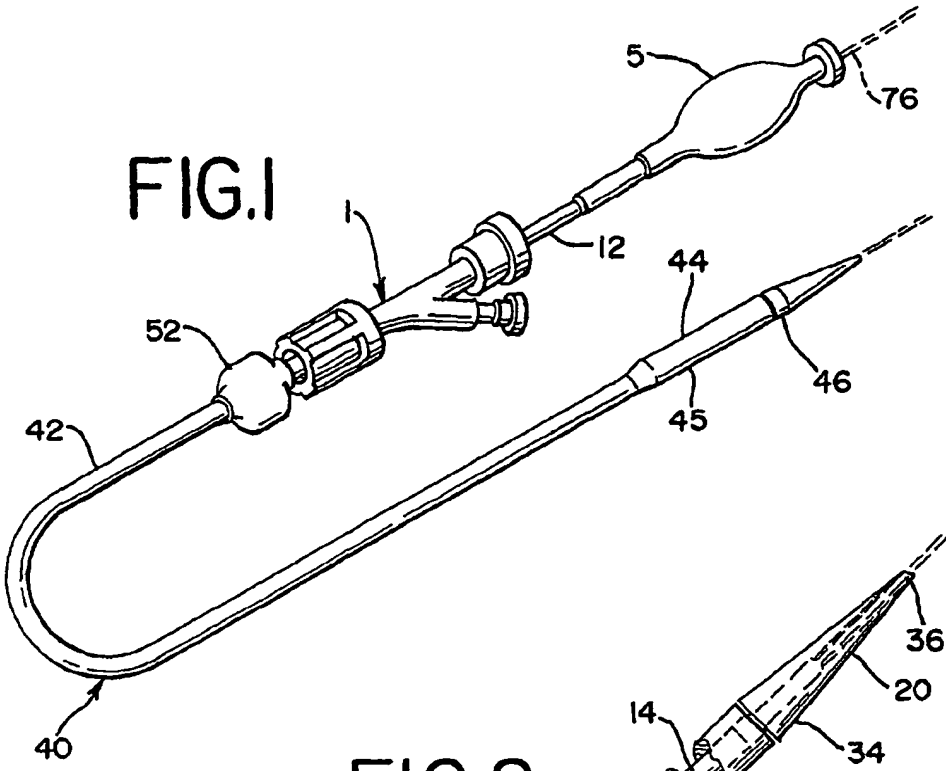


FIG.2

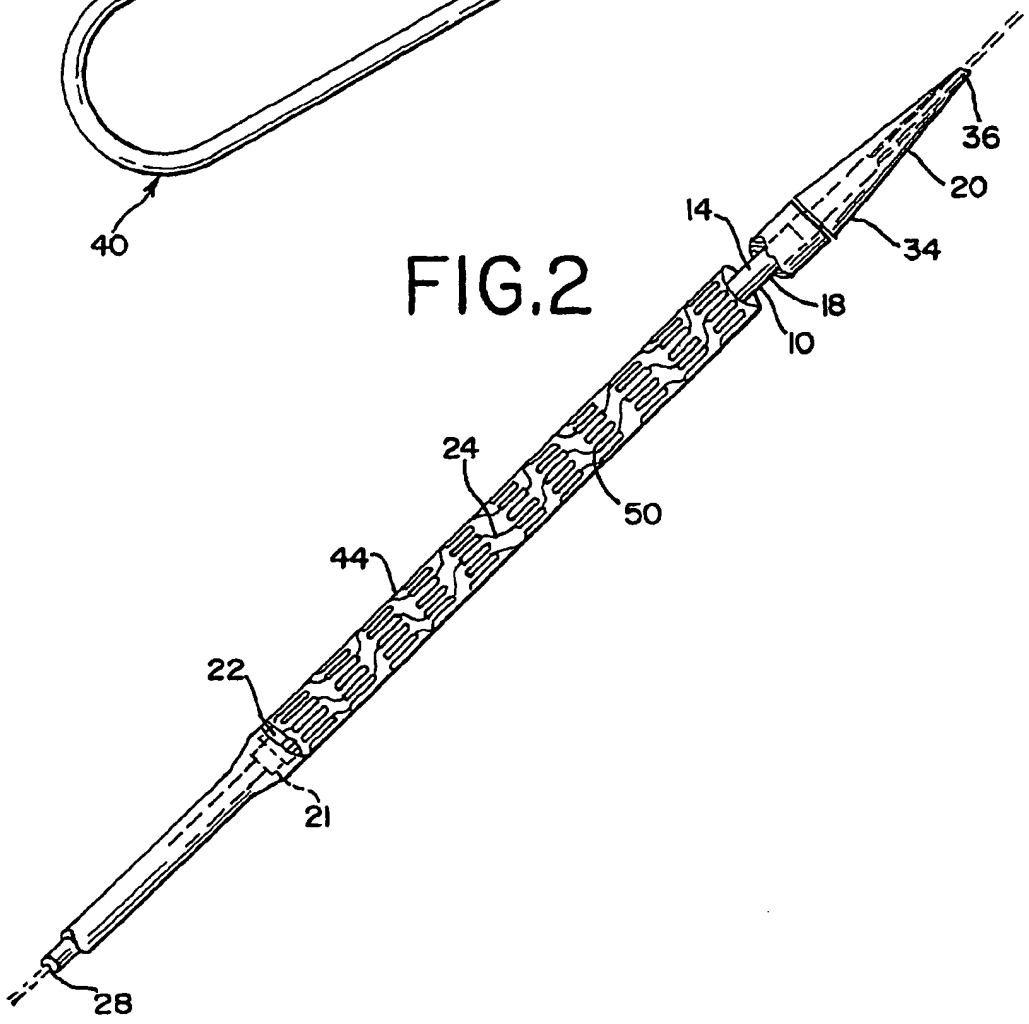
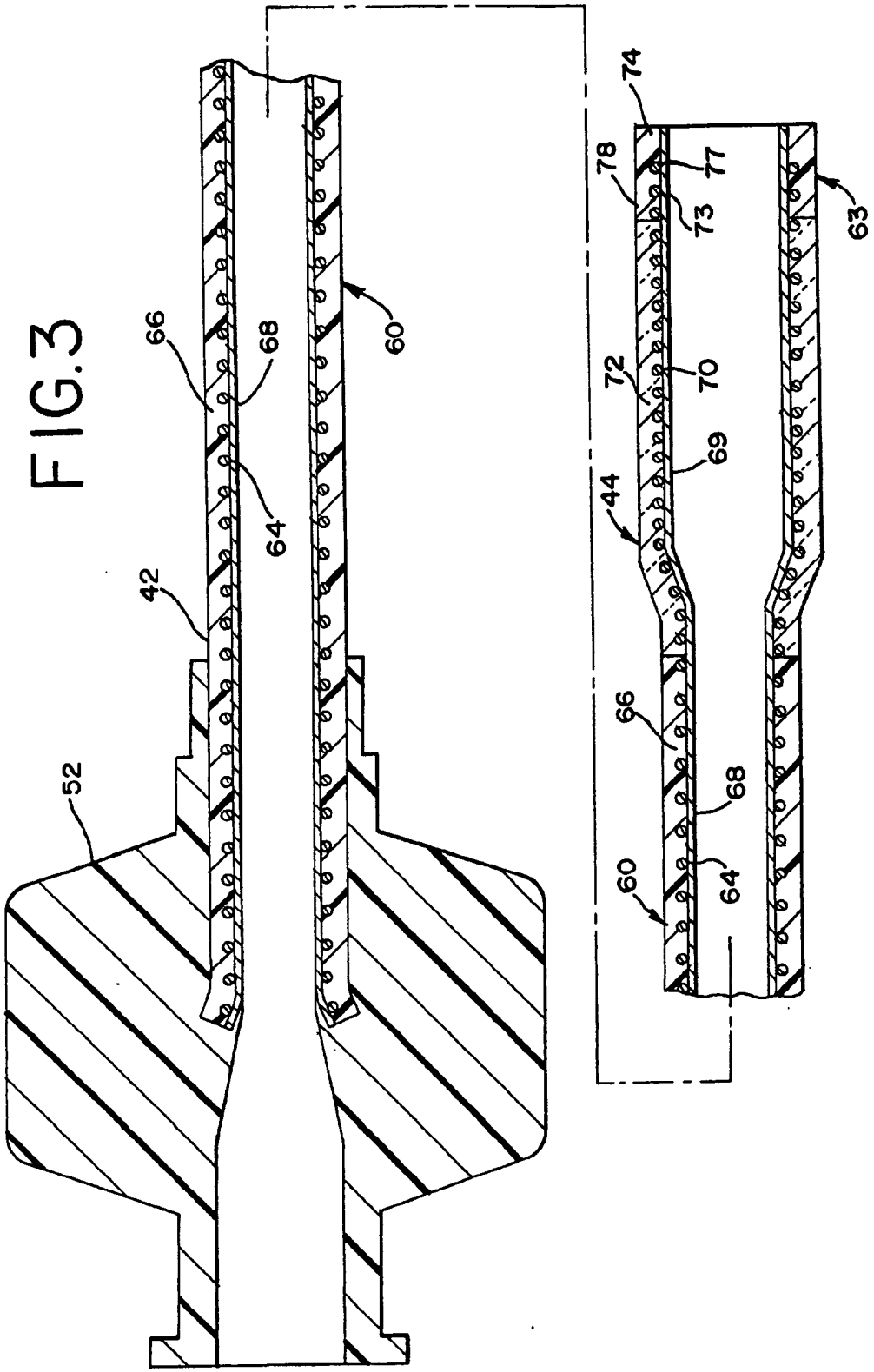


FIG.3



STENT DELIVERY SYSTEM HAVING DELIVERY CATHETER MEMBER WITH A CLEAR TRANSITION ZONE

RELATED PATENT APPLICATION

[0001] The present invention is an improvement of the stent delivery system disclosed in co-pending U.S. patent application Ser. No. 09/243,750, entitled, "A Delivery Apparatus For A Self Expanding Stent," filed Feb. 3, 1999, assigned to the same assignee as the subject patent application, and hereby incorporates by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to an expandable intraluminal medical device, for example a stent, for use within a body passageway for repairing blood vessels narrowed or occluded by disease. More particularly, the present invention relates to a system for delivering such stents.

BACKGROUND OF THE INVENTION

[0003] Percutaneous transluminal coronary angioplasty (PTCA)is a therapeutic medical procedure used to increase blood flow through the coronary artery and can often be used as an alternative to coronary by-pass surgery. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial stenosed lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer, or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

[0004] Recently, transluminal prostheses have been widely used in the medical arts for implantation in blood vessels, bilary ducts, or other similar organs of the living body. These prostheses are commonly known as stents and are used to maintain, open, or dilate tubular structures. An example of a commonly used stent is given in U.S. Pat. No. 4,733,665 filed by Palmaz on Nov. 7, 1985, which is hereby incorporated herein by reference. Such stents are often referred to as balloon expandable stents. Typically the stent is made from a solid tube of stainless steel. Thereafter, a series of cuts are made in the wall of the stent. The stent has a first smaller diameter which permits the stent to be delivered through the human vasculature by being crimped onto a balloon catheter. The stent also has a second, expanded diameter, upon the application, by the balloon catheter, from the interior of the tubular shaped member of a radially, outwardly extending.

[0005] However, such stents are often impractical for use in some vessels such as the carotid artery. The carotid artery is easily accessible from the exterior of the human body, and is often visible by looking at ones neck. A patient having a balloon expandable stent made from stainless steel or the like, placed in their carotid artery might be susceptible to severe injury through day to day activity. A sufficient force placed on the patient's neck, such as by falling, could cause the stent to collapse, resulting in injury to the patient. In order to prevent this, self-expanding stents have been proposed for use in such vessels. Self-expanding stents act like springs and will recover to their expanded or implanted configuration after being crushed.

[0006] One type of self-expanding stent is disclosed in U.S. Pat. No. 4,665,771, which stent has a radially and axially flexible, elastic tubular body with a predetermined diameter that is variable under axial movement of ends of the body relative to each other and which is composed of a plurality of individually rigid but flexible and elastic thread elements defining a radially self-expanding helix. This type of stent is known in the art as a "braided stent" and is so designated herein. Placement of such stents in a body vessel can be achieved by a device which comprise an outer catheter for holding the stent at its distal end, and an inner piston which pushes the stent forward once it is in position.

[0007] Other types of self-expanding stents use alloys such as Nitinol (Ni—Ti alloy) which have shape memory and/or superelastic characteristics in medical devices which are designed to be inserted into a patient's body. The shape memory characteristics allow the devices to be deformed to facilitate their insertion into a body lumen or cavity and then be heated within the body so that the device returns to its original shape. Superelastic characteristics on the other hand generally allow the metal to be deformed and restrained in the deformed condition to facilitate the insertion of the medical device containing the metal into a patient's body, with such deformation causing the phase transformation. Once within the body lumen the restraint on the superelastic member can be removed, thereby reducing the stress therein so that the superelastic member can return to its original un-deformed shape by the transformation back to the original phase.

[0008] Alloys having shape memory/superelastic characteristics generally have at least two phases. These phases are a martensite phase, which has a relatively low tensile strength and which is stable at relatively low temperatures, and an austenite phase, which has a relatively high tensile strength and which is stable at temperatures higher than the martensite phase.

[0009] When stress is applied to a specimen of a metal such as Nitinol exhibiting superelastic characteristics at a temperature above which the austenite is stable (i.e. the temperature at which the transformation of martensite phase to the austenite phase is complete), the specimen deforms elastically until it reaches a particular stress level where the alloy then undergoes a stress-induced phase transformation from the austenite phase to the martensite phase. As the phase transformation proceeds, the alloy undergoes significant increases in strain but with little or no corresponding increases in stress. The strain increases while the stress remains essentially constant until the transformation of the austenite phase to the martensite phase is complete. Thereafter, further increases in stress are necessary to cause further deformation. The martensitic metal first deforms

elastically upon the application of additional stress and then plastically with permanent residual deformation.

[0010] If the load on the specimen is removed before any permanent deformation has occurred, the martensitic specimen will elastically recover and transform back to the austenite phase. The reduction in stress first causes a decrease in strain. As stress reduction reaches the level at which the martensite phase transforms back into the austenite phase, the stress level in the specimen will remain essentially constant (but substantially less than the constant stress level at which the austenite transforms to the martensite) until the transformation back to the austenite phase is complete, i.e. there is significant recovery in strain with only negligible corresponding stress reduction. After the transformation back to austenite is complete, further stress reduction results in elastic strain reduction. This ability to incur significant strain at relatively constant stress upon the application of a load and to recover from the deformation upon the removal of the load is commonly referred to as superelasticity or pseudoelasticity. It is this property of the material which makes it useful in manufacturing tube cut self-expanding stents. The prior art makes reference to the use of metal alloys having superelastic characteristics in medical devices which are intended to be inserted or otherwise used within a patient's body. See for example, U.S. Pat. No. 4,665,905 (Jervis) and U.S. Pat. No. 4,925,445 (Sakamoto et al.).

[0011] Designing delivery systems for delivering self-expanding stents has proven difficult. One example of a prior art selfexpanding stent delivery system is shown in U.S. Pat. No. 4,580,568 issued to Gianturco on Apr. 8, 1986. This reference discloses a delivery apparatus which uses a hollow sheath, like a catheter. The sheath is inserted into a body vessel and navigated therethrough so that its distal end is adjacent the target site. The stent is then compressed to a smaller diameter and loaded into the sheath at the sheath's proximal end. A cylindrical flat end pusher, having a diameter almost equal to the inside diameter of the sheath is inserted into the sheath behind the stent. The pusher is then used to push the stent from the proximal end of the sheath to the distal end of the sheath. Once the stent is at the distal end of the sheath, the sheath is pulled back, while the pusher remains stationary, thereby exposing the stent and expanding it within the vessel.

[0012] However, delivering the stent through the entire length of the catheter can cause many problems, including possible damage to a vessel or the stent during its travel. In addition, it is often difficult to design a pusher having enough flexibility to navigate through the catheter, but also enough stiffness to push the stent out of the catheter. Therefore, it was discovered that pre-loading the stent into the distal end of the catheter, and then delivering the catheter through the vessel to the target site may be a better approach. In order to ensure proper placement of the stent within catheter, it is often preferred that the stent be pre-loaded at the manufacturing site. Except this in itself has posed some problems. Because the catheter exerts a significant force on the self-expanding stent which keeps it from expanding, the stent may tend to become imbedded within the inner wall of the catheter. When this happens, the catheter has difficulty sliding over the stent during delivery. This situation can result in the stent becoming stuck inside the catheter, or could damage the stent during delivery.

[0013] Another example of a prior art self-expanding stent delivery system is given in U.S. Pat. No. 4,732,152 issued to Wallsten et al. on Mar. 22, 1988. This patent discloses a probe or catheter having a self-expanding stent pre-loaded into its distal end. The stent is first placed within a flexible hose and compressed before it is loaded into the catheter. When the stent is at the delivery site the catheter and hose are withdrawn over the stent so that it can expand within the vessel. However, withdrawing the flexible hose over the stent during expansion could also cause damage to the stent.

[0014] For prior art delivery devices, the maximum outside diameter of the device was usually controlled by the diameter of the stent prior to deployment. Typically, the stent may only be compressed so much, and therefore its diameter is determined by the maximum diameter of the delivery device. For prior art devices, the diameter of the entire delivery device along its length is substantially uniform. Therefore, the outside diameter along the entire length of the device was its maximum diameter as required by the stent. That is, the overall outer diameter of the outer sheath for these devices is controlled by the size of the pre-loaded stent. As explained below, large sized outer sheaths can pose obstacles to the physician.

[0015] Often a sheath, such as, a guiding catheter, is used with these delivery devices as a conduit into the vasculature. Using fluoroscopy, the physician will often view the targeted site, pre-deployment and post-deployment, of the stent by injecting a radiopaque solution between the guiding catheter and the delivery device. The ability to view the image is controlled by the injection rate of the solution, which is dependent upon the amount of clearance between the guiding catheter and the outer sheath of the delivery device. A large outer sheath limits the amount of radiopaque solution which can pass through the guiding catheter, causing the physician to have a less clear image of the procedure.

[0016] Another problem associated with prior stent delivery systems is caused by the fact that prior to being inserted into the body the stent is entirely covered by an opaque delivery catheter and it is not possible for the physician to visually observe the stent prior to insertion into the body. For example, the physician is unable to visually observe the length of the stent. Often times the length of a stent is very critical to the performance of the stent depending upon the length of the obstruction. In addition, the physician is unable to visually observe the location or position of the stent with the catheter, and for that matter, the physician is unable to even visually confirm that a stent is present within the delivery catheter.

[0017] Therefore, there has been a need for a self-expanding stent delivery system which overcomes the above referenced problems associated with prior art delivery systems. Specifically, there has been a need for a self-expanding stent delivery system which allows the physician to visually observe the stent, and its characteristics, within the delivery catheter prior to insertion of the catheter within the body.

SUMMARY OF THE INVENTION

[0018] In accordance with one aspect of the present invention, there is provided a medical device delivery system for using an expandable medical device within the body which includes an outer sheath comprising an elongated tubular body member and a distal section having a proximal end

bonded to the distal end of the tubular body member. In addition, the distal section formed from a clear polymeric material, such as a clear nylon material, so as to make possible the visual inspection of an implantable medical device positioned beneath or within the distal section of the outer sheath. In addition, the delivery system includes an inner shaft located coaxially within the outer sheath and an implantable medical device located within the relatively clear distal section of the outer sheath. The inner shaft serves the purpose of providing for the delivery of the medical device.

[0019] In accordance with another aspect of the present invention there is provided a medical device delivery system for a self-expanding stent which includes an outer sheath having an elongated tubular body member and enlarged distal section. The distal section has a greater inside and outside diameter than the inside and outside diameter of the tubular body member. In addition, the enlarged distal section is formed from a relatively clear polymeric material such as a clear nylon material, so that a physician may visually observe the stent within the outer sheath prior to insertion of the outer sheath within the body of a patient. Also, the delivery system includes an inner shaft located coaxially within the outer sheath, and a self-expanding stent located within the relatively clear enlarged distal section of the outer sheath. The stent is maintained in frictional contact with the interior surface of the outer sheath in order to maintain the stent in a collapsed condition. In addition, the inner shaft is connected to the stent for delivering the stent at a desired location within the body.

[0020] In accordance with still another aspect of the present invention, there is provided a medical device delivery system which includes a catheter comprising a polymeric tubular body section and a flexible distal tubular section bonded to a body section. The distal tubular section is formed from a relatively clear polymeric material so that an implantable medical device, when placed within the catheter, may be visually inspected by a physician prior to insertion of the catheter within the body of a patient.

[0021] In accordance with still another aspect of the present invention, the flexible distal tubular section has an inner diameter and an outer diameter which are smaller than the inner diameter and outer diameter, of the polymeric tubular body section.

[0022] In accordance with still another aspect of the present invention, the catheter includes a distal tip which is comprised of a polymeric formulation containing from about 20 to 75 weight percent of a radiopaque agent so that the distal tip is substantially more radiopaque than the distal tubular section and the tubular body section of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] The foregoing and other aspects of the present invention will best be appreciated with reference to the detailed description of a preferred embodiment of the present invention shown in the accompanying drawings, wherein:

[0024] **FIG. 1** is a simplified perspective view of a stent delivery system in accordance with the present invention;

[0025] **FIG. 2** is a view similar to that of **FIG. 1** but showing an enlarged view of the distal end of the delivery system and it includes a cut-away section to illustrate a stent loaded therein; and,

[0026] **FIG. 3** is a cross sectional view of the outer sheath shown in **FIGS. 2 and 3** illustrated in more detail.

DETAILED DESCRIPTION OF THE INVENTION

[0027] Referring now to the Figures wherein like numerals indicate the same element throughout the views, there is shown in **FIGS. 1 and 2** a self-expanding stent delivery system **1** made in accordance with the present invention. System **1** comprises inner and outer coaxial tubes. The inner tube will be referred to as the shaft **10** and the outer tube will be referred to as the sheath **40**. Shaft **10** has proximal and distal ends **12** and **14** respectively. The proximal end **12** of the shaft has a Luer guidewire hub **5** attached thereto. The shaft **10** has a proximal portion which is preferably made from a relatively stiff material such as stainless steel, Nitinol, or any other suitable material known to those of ordinary skill in the art. The shaft **10** also includes a distal portion **18** which is preferably made from a co-extrusion high density polyethylene for the inner portion and polyamide for the outer portion. Other suitable materials for distal portion **18** known to those of ordinary skill in the art include polyurethane, polyamide, polyetheretheketone, and Nitinol. These materials may be utilized as single or multi-layer structures, and may also include reinforcement wires, braid wires, coils, filaments or the like.

[0028] The distal end **14** of the shaft **10** includes a distal tip **20** attached thereto. Distal tip **20** can be made from any number of materials known in the art including polyamide, polyurethane, polytetrafluoroethylene, and polyethylene including multi-layer or single layer structures. The distal tip **20** has a proximal end **34** whose diameter is substantially the same as the outer diameter of the sheath **40** which is immediately adjacent thereto. The distal tip tapers to a smaller diameter from its proximal end **34** to its distal end **36**, wherein the distal end **36** of the distal tip has a diameter smaller than the inner diameter of the sheath. Tip **20** helps to prevent blood from entering the sheath **40** as the system **1** is being navigated through the body vessels. Attached to distal end **14** of the shaft **10** is a stop **22** which is proximal to the distal tip **20** and stent **50**. Stop **22** can be made from any number of materials known in the art, including stainless steel, and is even more preferably made from a highly radiopaque material such as platinum, gold, tantalum, or radiopaque filled polymer. The stop can be attached to shaft **10** by mechanical or adhesive bonding, or by any other means known to those skilled in the art. Preferably, the diameter of stop **22** is large enough to make sufficient contact with the loaded stent **50** at its end without making frictional contact with the inner layer of the outer sheath **40**. The stop **22** helps to "push" the stent out of the sheath during deployment, by preventing the stent from migrating proximally within the sheath **40** during retraction of the sheath for stent deployment. Proximal to stop **22** is sleeve **21**, which can be made from any number of materials known to those skilled in the art including plastic. Sleeve **21** is attached to shaft **10** immediately proximal to stop **22** by any number of ways known to those skilled in the art including thermal or mechanical bonding. Sleeve **21** acts to reinforce stop **22** during deployment of the stent **50**. Sleeve **21** is large enough to make sufficient contact with stop **22** in order to reinforce stop **22**. However, it is also preferably small enough not to interfere with the taper of outer sheath **40** when the inner shaft **10** is inside the outer sheath **40**. During deployment,

the outer sheath **40** is moved in a proximal direction relative to the stationary inner shaft **10**. The radiopaque stop **22** also aides in positioning the stent within the target lesion during deployment within a vessel, as is described below.

[0029] A stent bed **24** is defined as being that portion of the shaft between the distal tip **20** and the stop **22** (**FIG. 2**). The stent bed **24** and the stent **50** are coaxial so that the portion of shaft **18** comprising the stent bed **24** is located within the lumen of stent **50**. The stent bed **24** makes minimal contact with stent **50** because of the space which exists between the inner shaft **10** and the outer sheath **40**. As the stent is subjected to temperatures at the austenite phase transformation it attempts to recover to its programmed shape by moving outwardly in a radial direction within the sheath. The outer sheath **40** constrains the stent as will be explained later herein.

[0030] The shaft **10** has a guidewire lumen **28** extending along its length, where the guidewire enters through the guidewire hub **5** and exits through its distal tip **20**. This construction allows the shaft **10** to receive a guidewire **76** much in the same way that a balloon angioplasty catheter receives a guidewire. Such guidewires are well known in the art and help to guide catheters and other medical devices through the vasculature of the body.

[0031] Sheath **40** is preferably a polymeric catheter and has a proximal end **42** terminating at a Luer hub **52**. Sheath **40** also has a distal end **45** which terminates at the proximal end **34** of distal tip **20** of the shaft **10**, when the stent **50** is in an unexpanded position as shown in **FIG. 2**. As will be explained below, the stent is fully deployed when the marker band **46** is proximal to radiopaque stop **22**, thus indicating to the physician that it is now safe to remove the system **1** from the body.

[0032] As detailed in **FIGS. 2 and 3**, the distal end **45** of sheath **40** includes an enlarged section **44**. Enlarged section **44** has larger inside and outside diameters than the inside and outside diameters of the sheath proximal to section **44**. Enlarged section **44** houses the pre-loaded stent **50**, the stop **22**, sleeve **21**, and the stent bed **24**. Proximal to sleeve **21**, the outer sheath **40** tapers proximally to a smaller size diameter. One particular advantage to this invention can best be described by referring to **FIG. 3**. As seen in those drawings, the reduction in the size of the outer diameter of sheath **40** proximal to enlarged section **44** results in an increase in the clearance between the delivery device **1** and a guiding catheter. The tapering of sheath **40** allows for higher injection rates of radiopaque fluid, both before and after deployment of the stent, when the enlarged section **44** is placed inside a guiding catheter.

[0033] **FIG. 3** illustrates in more detail the construction of the delivery sheath which includes a tubular body section **60**, which is bonded to the enlarged distal section **44**, which is in turn bonded to a distal tip **63**. As illustrated, the Luer hub **52** is attached to the proximal end **42** of the tubular body section **60**.

[0034] More particularly, the tubular body section **60** is comprised of an inner teflon layer **68**, stainless steel braiding **64** applied over the inner teflon layer **68** and a top coat **66** applied over and bonded to the stainless steel braiding **64**. The top coat **66** is preferably formed of an opaque nylon material and preferably includes a very minor amount of a radiopaque agent, such as less than about 20 weight percent of a polymeric radiopaque agent, such as bismuth trioxide or bismuth subcarbonate. The tubular body section **60** is bonded, preferably by heat bonding techniques, to the enlarged distal section **44** which is formed of an inner teflon layer **69** having stainless steel braiding **70** disposed on the teflon layer **69**, and a top coat **72** bonded to the stainless steel braiding **70**. Top coat **72** is preferably formed from nylon material, but most importantly the enlarged distal section **44** is formed of a material which is completely clear so that a medical device to be delivered, such as an expandable stent, may be visually inspected through the side wall of the distal section **44**. Preferably, the top coat **72** is formed of a clear nylon material.

[0035] The enlarged distal section **44** is then bonded preferably by use of a heat seal, to the distal tip **63**. The distal tip **63** also includes an inner teflon layer **73**, stainless steel braiding **77** which extends longitudinally into a portion of the distal tip **63**, and a top coat **78** which is bonded to the stainless steel braiding **77**. The top coat **78** is preferably formed of nylon material which includes the addition of a relatively high level of a radiopaque filler material i.e. on the order of about 20 to 75 weight percent of a polymeric radiopaque agent, such as powdered bismuth trioxide or bismuth subcarbonate, in order to provide a high level of radiopacity at the distal tip of the catheter.

[0036] The catheter used with the medical delivery system of the present invention may be formed from any flexible biocompatible material, such as a polymer material or a thin metallic material. Also, the catheter may be formed of materials of various durometer, however the top coat **72** of the enlarged distal section **44** is formed from nylon having a durometer of about 40 D, and the top coat **78**, of the distal tip **63** is formed of a nylon having a durometer of about 40 D to 75 D.

[0037] With this construction, it is possible to visually inspect the implantable medical device, such as an implantable stent, from outside of the catheter to thereby confirm that the medical device is properly placed within the catheter, that the medical device is of the proper length, and that the medical device is properly seated within the enlarged distal section of the catheter. Thus, the stent may be inspected during the manufacturing process to make certain that the stent is properly seated within the catheter. In addition, a physician may inspect the catheter system to ascertain whether, in fact, a stent has been placed into the delivery catheter and may visually check the length of the stent prior to inserting the catheter into the body.

[0038] The above description of a preferred embodiment has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of the application, which is as defined in the claims below:

That which is claimed is:

1. A medical device delivery system for a self-expanding stent comprising:

an outer sheath comprising an elongated tubular body member having distal and proximal ends and an inside and outside diameter; and an enlarged distal section having an inside and outside diameter and a distal end, and a proximal end bonded to the distal end of the tubular body member, said distal section having a

greater inside and outside diameter than said inside and outside diameter of said tubular body member, and said enlarged distal section being formed from a relatively clear polymeric material;

an inner shaft located coaxially within said outer sheath, said shaft having a distal end and a proximal end; and

a self-expanding stent located within said relatively clear distal section of said outer sheath, said stent making frictional contact with said outer sheath, and said shaft connected to said stent for delivery of said stent.

2. A medical device delivery system as defined in claim 1 wherein said sheath includes a flexible distal tip bonded to the enlarged distal section, said distal tip comprising a polymeric formulation containing from about 20 to 75 weight percent of a polymeric radiopaque agent to be substantially more radiopaque than the distal tubular section and the tubular body member of the sheath.

3. A medical device delivery system as defined in claim 2 wherein said elongated tubular body member is comprised of a polymeric formulation containing less than about 20 weight percent of radiopaque agent to be substantially less radiopaque than the distal tip.

4. A medical device delivery system as defined in claim 2 wherein said enlarged distal section is comprised of a clear nylon polymer.

5. A medical device delivery system as defined in claim 4 wherein said elongated tubular body member is comprised of an opaque nylon material.

6. A medical device delivery system for a self-expanding stent comprising:

an outer sheath comprising an elongated tubular body member having distal and proximal ends; and a distal section having a distal end, and a proximal end bonded to the distal end of the tubular body member, and said distal section being formed from a relatively clear polymeric material;

an inner shaft located coaxially within said outer sheath, said shaft having a distal end and a proximal end; and

a self-expanding stent located within said distal section of said outer sheath, said stent making frictional contact with said outer sheath, and said shaft connected to said stent for delivery of said stent.

7. A medical device delivery system as defined in claim 6 wherein said sheath includes a flexible distal tip bonded to the distal section, said distal tip comprising a polymeric formulation containing from about 20 to 75 weight percent of a polymeric radiopaque agent to be substantially more radiopaque than the distal section and the tubular body member of the sheath.

8. A medical device delivery system as defined in claim 7 wherein said elongated tubular body member is comprised of a polymeric formulation containing less than about 20 weight percent of a radiopaque agent to be substantially less radiopaque than the distal tip.

9. A medical device delivery system as defined in claim 6 wherein said distal section is comprised of a clear nylon polymer.

10. A medical device delivery system including a sheath comprising a polymeric tubular body member and a flexible distal tubular section bonded to the tubular body member, the distal tubular section is formed from a relatively clear polymeric material so that an implantable medical device when placed within the sheath may be viewed, a flexible distal tip bonded to the distal tubular section, said distal tip comprising a polymeric formulation containing from about 20 to 75 weight percent of a polymeric radiopaque agent to be substantially more radiopaque than the distal tubular section and the tubular body member of the sheath.

11. A medical device delivery system as defined in claim 10 wherein the tubular body member and the distal tubular section have inside and outside diameters and in which the diameter of the inside and outside diameter of the distal tubular section is greater than the inside and outside diameter of the tubular body member of the sheath.

12. A medical device delivery system for an implantable medical device comprising:

an outer sheath comprising an elongated tubular body member having distal and proximal ends and an inside and outside diameter; and an enlarged distal section having an inside and outside diameter and a distal end, and a proximal end bonded to the distal end of the tubular body member, said distal section having a greater inside and outside diameter than said inside and outside diameter of said tubular body member, and said enlarged distal section being formed from a relatively clear polymeric material;

an inner shaft located coaxially within said outer sheath, said shaft having a distal end and a proximal end; and an implantable medical device located within said enlarged distal section of said outer sheath, said medical device making frictional contact with said outer sheath, and said shaft connected to said medical device for delivery of said medical device.

13. A medical device delivery system as defined in claim 12 wherein said sheath includes a flexible distal tip bonded to the distal section, said distal tip comprising a polymeric formulation containing from about 20 to 75 weight percent of a polymeric radiopaque agent to be substantially more radiopaque than the distal section and the tubular body member of the sheath.

14. A medical device delivery system as defined in claim 13 wherein said elongated tubular body member is comprised of a polymeric formulation containing less than about 20 weight percent of a radiopaque agent to be substantially less radiopaque than the distal tip.

15. A medical device delivery system as defined in claim 12 wherein said enlarged distal section is comprised of a clear nylon polymer.

16. A medical device delivery system as defined in claim 14 wherein said elongated tubular body member is comprised of an opaque nylon material.

* * * * *

US006368344B1

(12) **United States Patent**
Fitz

(10) **Patent No.: US 6,368,344 B1**
(45) **Date of Patent: Apr. 9, 2002**

(54) **STENT DEPLOYMENT SYSTEM WITH REINFORCED INNER MEMBER**

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(73) Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(52) **U.S. Cl.** **623/1.11**; 606/108
(58) **Field of Search** 623/1.11, 1.23; 606/108, 198; 604/264, 524, 525, 526, 527

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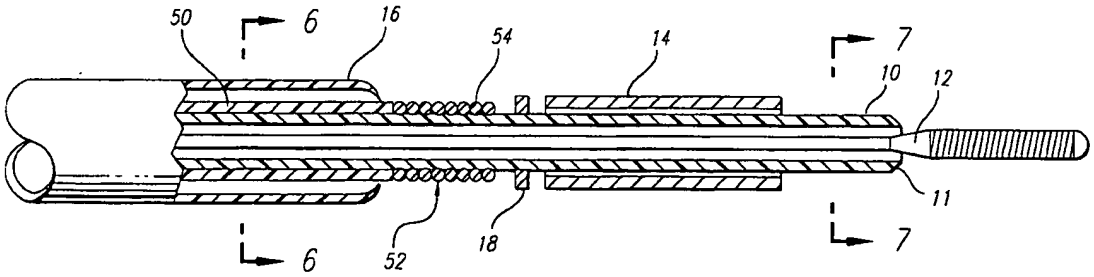
(74) *Attorney, Agent, or Firm*—Fulwider Patton Lee & Utecht, LLP

(57) **ABSTRACT**

A stent deployment system with a reinforced inner member is disclosed. The system has a self-expanding stent in a contracted condition disposed on the distal end of a delivery catheter and a retractable sheath covering the stent. The delivery catheter is advanced through a guide catheter to a desired location within a patient's body lumen. Once the stent is at the target site, the sheath is retracted by pulling back on the stem to expose the self-expanding stent. The reinforced inner member provides longitudinal compression resistance for the delivery catheter, while allowing for flexibility for navigation through a tortuous vasculature.

19 Claims, 3 Drawing Sheets



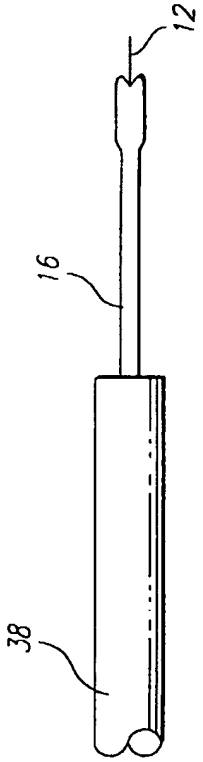


FIG. 1

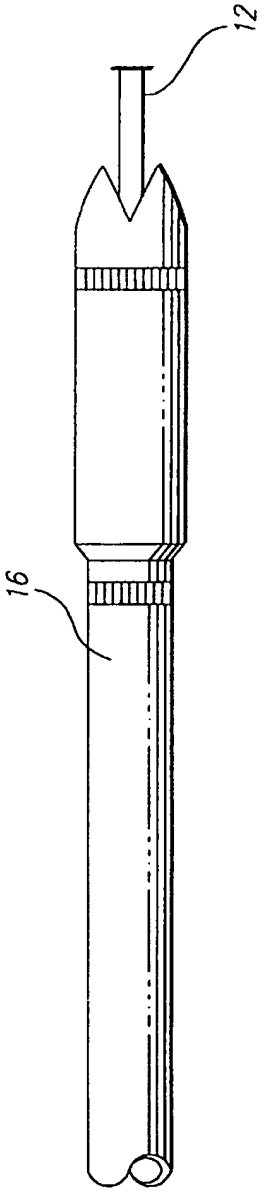


FIG. 2

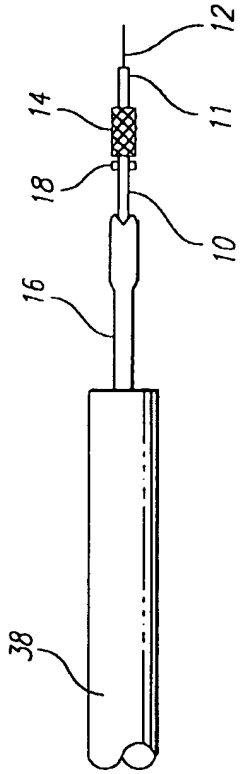


FIG. 3

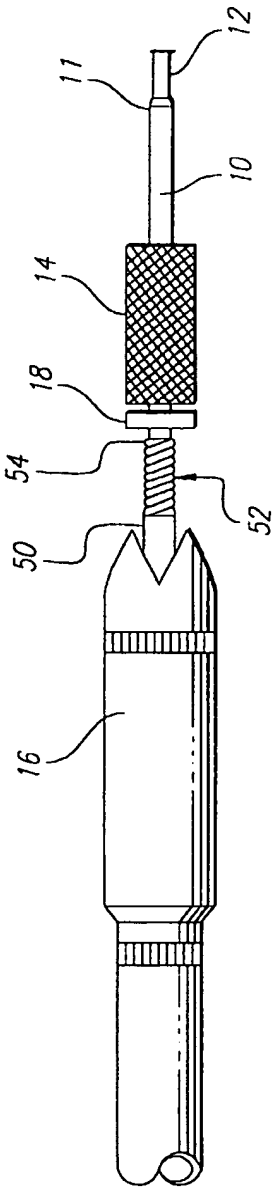


FIG. 4

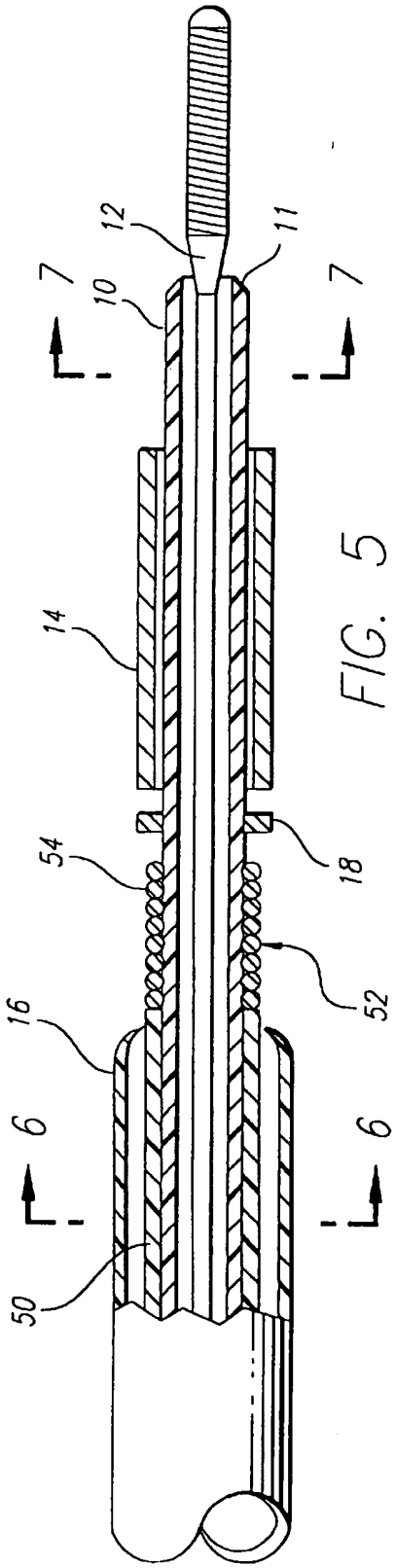


FIG. 5

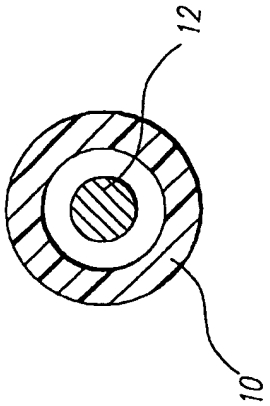


FIG. 7

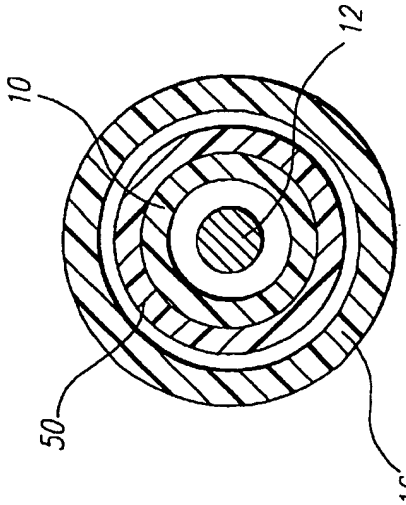


FIG. 6

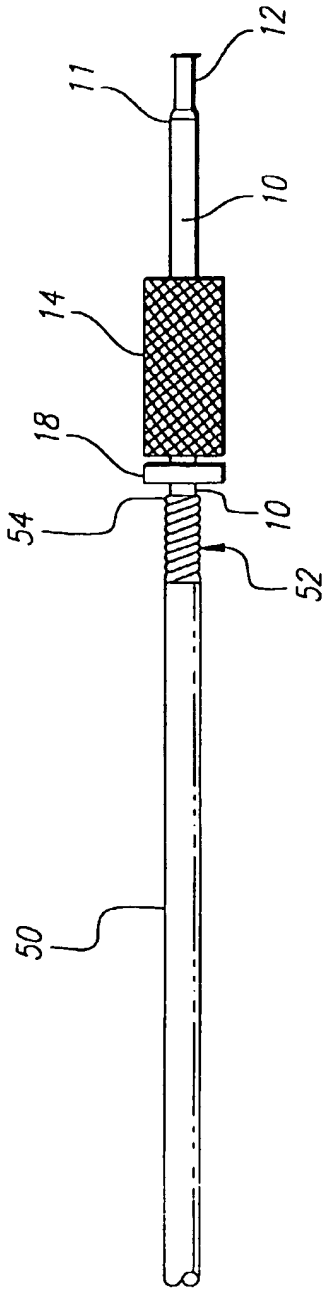


FIG. 8

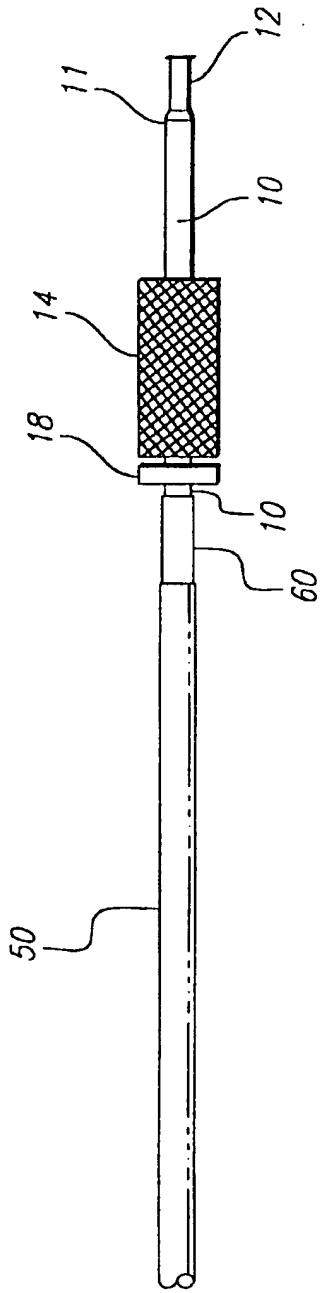


FIG. 9

STENT DEPLOYMENT SYSTEM WITH REINFORCED INNER MEMBER

BACKGROUND OF THE INVENTION

The present invention relates in general to the delivery of stents into a body lumen, such as a blood vessel, to maintain the patency thereof. More particularly, the present invention relates to an improved stent delivery system that can accurately deliver a self-expanding stent within a body lumen.

In a medical procedure known as percutaneous transluminal coronary angioplasty (PTCA), a balloon catheter is used to dilate the lumen of a coronary artery which has become narrowed or restricted due to the accumulation of atherosclerotic plaque along the artery wall. In the PTCA procedure, a balloon catheter is advanced through the vasculature to the stenosis and the balloon is inflated to radially compress the atherosclerotic plaque against the inside of the artery wall. The balloon is then deflated so that the dilation catheter can be removed and blood flow resumed through the dilated artery.

Occasionally, the inflation of the balloon within the artery lumen will dissect either the stenotic plaque or the intima of the blood vessel or both. After the balloon is deflated and removed, blood can flow between the arterial wall and the dissected lining thereby constricting the flow passage or causing a section of the dissected lining, commonly called an "intimal flap," to be forced into the flow passageway. In the event of partial or total occlusion of an artery by a dissected arterial lining, the patient is put in an extremely dangerous situation requiring immediate medical attention.

Another problem which frequently arises after an angioplasty procedure is the appearance of a restenosis at or near the site of the treated artery. The restenosis may appear due to the accumulation of additional atherosclerotic plaque or may be the result of weakened arterial walls which have collapsed inward to restrict blood flow. When restenosis appears, the treated patient may require an additional angioplasty procedure or other treatment such as by-pass surgery, if an additional angioplasty procedure is not warranted.

Due to the problems caused by dissections of the arterial lining or the appearance of restenosis, much research has been performed on ways to maintain the patency of an artery after the angioplasty procedure is completed. In recent years, expandable endoprosthetic devices, commonly called "stents," have gained widespread acceptance as a means to support the arterial walls and maintain the patency of a treated vessel. Stents are generally cylindrically shaped intravascular devices which are placed within a damaged artery to hold it open and maintain unimpeded blood flow. Stents prevent dissected arterial linings from occluding an artery by pressing the dissected tissue against the arterial wall until natural healing results in the re-securing of the dissected tissue to the arterial wall. Stents also prevent the appearance of restenosis in the treated vessel by supporting the weakened arterial walls.

Various means have been developed for delivering and implanting intravascular stents within a body lumen. One common method involves compressing or otherwise reducing the diameter of a self-expanding stent, mounting the compressed stent on the distal end of a delivery catheter, placing a tubular sheath over the stent to restrain the stent in the contracted condition, and advancing the catheter through the patient's vasculature to the desired location. Once the stent is properly positioned, the stent is exposed by withdrawing the sheath proximally with respect to the stent, advancing the stent distally with respect to the sheath, or performing a combination of both. Once free from the sheath, the self-expanding stent expands against the arterial walls to thereby hold open the artery or other body lumen into which it is placed.

Other examples of stent delivery systems include U.S. Pat. No. 5,026,377 to Burton et al. Burton discloses an instrument for the deployment or retraction of a self expanding stent in a body canal, which comprises an elongated tubular outer sleeve having disposed therein an elongated core which is moveable relative to the sleeve and has a grip member formed at or near its distal end, which grip member is adapted to releasably hold a self-expanding stent within the outer sleeve. U.S. Pat. No. 5,190,058 to Jones et al. discloses a method of using a temporary stent catheter. The catheter comprises a catheter tube having a distal end and a proximal end; an elongated balloon inflatable by fluid pressure attached to the catheter tube near its distal end; a stent having a tubular configuration attached to the catheter tube near its distal end and surrounding the balloon; a pressurization device near the proximal end of the catheter tube for inflating and deflating the balloon, whereby the stent may be pressed against the wall of a blood vessel by the balloon and the balloon may be subsequently deflated; a restriction device near the proximal end of the catheter tube for maintaining the stent in an expanded condition and for subsequently effecting the radial contraction of the stent whereby it may be removed from the blood vessel.

U.S. Pat. No. 5,201,757 to Heyn et al. discloses an apparatus for deploying a radially self-expanding stent that includes proximal and distal sleeves respectively containing proximal and distal end portions of the stent in a reduced radius delivery configuration. Once the stent and sleeves are positioned at the intended fixation site, the sleeves are moved axially with respect to one another to permit radial self-expansion of the stent only over its medial region, while the sleeves continue to contain the axially outward regions of the stent. Upon sufficient movement of the sleeves axially relative to each other, the stent becomes totally free of the sleeves. U.S. Pat. No. 5,290,295 to Querals et al. discloses a tool for the intraluminal insertion and deployment of a tubular graft within a blood vessel, that is constructed from a flexible insertion shaft with a tapered distal end, a tubular sheath, a deployment slider and a safety locking tube.

U.S. Pat. No. 5,391,172 to Williams et al. discloses a stent delivery system with coaxial catheter handle. The catheter handle provides relative motion between the outer sheath of a stent delivery catheter and an underlying catheter, via a thumb switch, to enable the outer sheath to withdraw from over the underlying catheter and expose a vascular prosthesis.

U.S. Pat. No. 5,507,768 to Lau et al. discloses a stent delivery method and system that includes an elongated delivery sheath and a catheter disposed within an outer lumen of the sheath having an expandable member on its distal extremity. An expandable stent is mounted on the expandable member and the distal portion of the sheath tapers down and is tucked within an elastic cone during transport of the stent to a stenotic region. A manipulating device is provided on the proximal end of the delivery system to effect relative axial movement between the sheath and the catheter so as to expose the stent mounted on the expandable member on the catheter within a body lumen, such as a coronary artery, and allow the expansion of the stent by the expansion of the expandable member.

One of the difficulties with some prior stent deployment systems involves deploying the stent at the precise, desired

location within the body lumen. Typically, a self-expanding stent is mounted on the distal end of a delivery catheter that is attached to a manipulator handle outside the patient's body. The stent is deployed by actuating a mechanism on the manipulator handle, such as a thumb plate, which is hand operated by the physician. When the thumb plate is withdrawn proximally relative to the manipulator handle, the sheath is withdrawn proximally relative to the catheter and stent.

Problems can arise when the sheath is retracted proximally by the application of a pulling force. The friction between both the stent and the sheath and the catheter and the sheath must be overcome by the pulling force in order for the stent to be deployed. The tensile force exerted on the outer sheath will be opposed by an equivalent compressive force exerted on the catheter. When compression of the catheter occurs, the sheath may not retract relative to the stent.

Alternatively, the sheath may retract after the catheter has already been compressed a certain amount. Consequently, the stent may not be deployed precisely in the desired location. Physicians have very little tolerance when it comes to inaccuracy of stent placement. A placement error of only millimeters is often considered to be intolerable. A poorly placed stent may do more harm than good and can be very difficult to retrieve once deployed. Therefore, it is critical to position the stent accurately on the first attempt.

A metal hypotube can be used throughout the length of the catheter to reinforce the catheter and increase the compression resistance of the catheter. However, the use of a hypotube at the distal end of the catheter can provide for a device that is generally not flexible enough to properly navigate through tortuous areas of the vasculature. Furthermore, some prior art attempts have produced catheters that are bulky and thick. These configurations may be prone to dislodging arterial plaque and are not ideal for navigation through a tortuous vasculature.

What has been needed and heretofore unavailable is a stent deployment system for self-expanding stents that provides a means to prevent unwanted movement of the stent and to provide greater accuracy of stent placement within a body lumen. The device should be highly resistant to compressive forces yet maintain enough flexibility for navigation through the highly tortuous vasculature. Additionally, the system should be relatively easy to use and manufacture. The present invention satisfies these needs and others.

As used herein, the terms "proximal," "proximally" and "proximal direction" when used with respect to the invention are intended to mean moving away from or out of the patient, and the terms "distal," "distally" and "distal direction" when used with respect to the invention are intended to mean moving toward or into the patient. These definitions will apply with reference to apparatus, such as catheters, guide wires, stents and the like.

SUMMARY OF THE INVENTION

The invention provides for a stent deployment system for delivering a self-expanding stent within a body lumen. The system provides for both resistance to longitudinal compression while at the same time retains adequate flexibility for navigation through a tortuous vasculature.

In one aspect of the invention, there is provided a stent deployment system for delivery of a self-expanding stent within a body lumen. The system includes a delivery assembly and a guide catheter. The delivery assembly includes an inner tubular member. The distal end of the inner tubular member is configured to receive over an exterior thereof the self-expanding stent. At least a portion of the inner tubular member includes a first reinforcing element connected thereto. The first reinforcing element provides longitudinal compression resistance for the inner tubular member, while allowing for flexibility for navigation through a tortuous vasculature. The delivery assembly also includes an elongated sheath formed with a lumen to slidably receive the inner tubular member. The guide catheter is formed with a lumen for receiving the delivery assembly therein.

The stent delivery system can be used to accurately deliver a stent to a desired location within a patient's vasculature system or other body lumen by preventing unwanted axial motion of the self-expanding stent during the deployment process. The stent delivery system is safe, easy-to-use and can be quickly and easily removed after the stent has been deployed. The present invention is designed primarily for use in the carotid arteries; however, the system also can be used to treat other vessels. Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view of a preferred embodiment stent delivery system of the present invention.

FIG. **2** is a partial and magnified elevational view of the distal end of the stent delivery system depicted in FIG. **1**.

FIG. **3** is an elevational view similar to FIG. **1**, but showing the sheath in its withdrawn position.

FIG. **4** is a partial and magnified view of the distal end of the stent delivery system depicted in FIG. **3**.

FIG. **5** is a partial and magnified view, in partial longitudinal cross-section, the distal end of the stent delivery system of FIG. **3**.

FIG. **6** is a transverse cross-sectional view taken along line **6—6** of FIG. **5**, depicting the hypotube, catheter and guide wire contained within a lumen of the sheath.

FIG. **7** is a transverse cross-sectional view taken along line **7—7** in FIG. **5**, depicting the guide wire slidably disposed within the catheter lumen.

FIG. **8** is a partial and elevational view of the present invention stent delivery system, depicting the first and second reinforcing elements.

FIG. **9** is partial and elevational view of an alternative embodiment of the present invention stent delivery system.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the exemplary drawings wherein like reference numerals indicate like or corresponding elements among the figures, the present invention includes a stent deployment system for treating vessels in, for example, the carotid arteries and other vessels in the body. Frequently, after balloon angioplasty has been performed to dilate a stenosis in the lumen of a vessel, a self-expanding stent is deployed at the treated site to aid in the healing of dissected arterial lining and to prevent restenosis.

Typically, a self-expanding stent is delivered and deployed by first compressing the stent, mounting the stent at the distal end of a delivery catheter and slidably disposing the catheter and stent within the lumen of a sheath to hold the stent in a contracted condition. Once the catheter and

stent are advanced to the desired location within a body lumen, the sheath is retracted to expose the self-expanding stent thereby allowing it to expand against the vessel wall. Examples of stent delivery systems are disclosed in, for example, U.S. Pat. Nos. 5,391,172 to Williams et al., and 5,507,768 to Lau et al., whose entire contents are hereby incorporated by reference.

As mentioned previously, in order to retract the sheath, the friction between both the stent and the sheath and the catheter and the sheath must be overcome by the pulling force used on the sheath. The tensile force exerted on the sheath will be opposed by an equivalent compressive force exerted on the catheter. When compression of the catheter occurs, one of two things may happen. The sheath may not retract relative to the stent. Alternatively, the sheath may retract after the catheter has already been compressed a certain amount. Consequently, the axial position of the stent might shift within the body lumen. This will cause the stent to be deployed in a different location than originally intended and thus not cover all of the target area. If the physician tries to compensate for the axial movement of the stent while attempting to retract the sheath, the physician may move the stent distally during deployment. This can cause the ends of the stent to tear into the body lumen wall.

The use of a metal hypotube throughout the length of the catheter can reinforce the catheter and increase the compression resistance of the catheter. However, the use of a hypotube at the distal end of the catheter can provide for a device that is generally not flexible enough to properly navigate through tortuous areas of the vasculature. It is therefore an object of the present invention to solve the accuracy problems associated with the prior art method of delivering and deploying self-expanding stents.

FIGS. **1–9** illustrate an exemplary stent deployment system that embodies features of the present invention. In the elevational views of FIGS. **1–4**, the present invention delivery system includes an inner tubular member, such as delivery catheter **10**, with a lumen therethrough adapted to receive a guide wire. The delivery catheter has proximal and distal ends and is configured to receive over an exterior thereof self-expanding stent **14**. The stent preferably has superelastic (SE) characteristics and may be made of NITINOL® nickel-titanium alloy or any other suitable material. Stents are known in the art and stent **14** can be of any suitable design. A guide wire **12** is slidably disposed within a lumen of delivery catheter **10**, and the stent is mounted on distal end **11** of the delivery catheter.

As best seen in FIG. **4**, delivery catheter **10** preferably has an elongated catheter body with at least one optional stop **18** that is immobile and located on a periphery near distal end **11** but proximally to stent **14** to prevent the stent from moving proximally relative to the delivery catheter. The stop can be an annular protrusion, a simple projection or the like to block the proximal movement of the stent.

The delivery catheter **10** and stent **14** are slidably disposed within elongated tubular sheath **16**, that holds stent **14** in a contracted condition during advancement through the patient's vasculature. It is contemplated that the sheath can be formed with different shapes. A means can be provided, such as including a manipulator handle, at the proximal end of the delivery system to effect relative axial movement between the delivery catheter and the sheath. Some examples of means that can be used with the present invention in order to effect relative axial movement between the delivery catheter and the sheath are described in U.S. patent application Ser. No. 09/307,177 by Fitz entitled "STENT DELIVERY SYSTEM", filed, May 7, 1999, and U.S. patent application Ser. No. 09/313,780 by Stack et al. entitled "SELF-EXPANDING STENT WITH ENHANCED DELIVERY PRECISION AND STENT DELIVERY SYSTEM", filed May 17, 1999, which are incorporated herein in their entirety by reference. The novel features of the present invention can be used in conjunction with the inventions disclosed in these applications.

FIGS. **1** and **2** show the delivery assembly as it exists during advancement through the vasculature with elongated sheath **16** at least partially covering stent **14**. The sheath has proximal and distal ends and is formed with a lumen to slidably receive delivery catheter **10**. The sheath is formed with a cylindrical body of a first diameter and can include an open-ended receptacle, with a second diameter that is larger than the first diameter, at the distal end for receiving the stent. The sheath preferably has an inner diameter large enough to accommodate the delivery catheter and to allow free longitudinal movement therein. FIGS. **3** and **4** show the delivery system after sheath **16** has been withdrawn proximally relative to the delivery catheter to expose the stent.

FIG. **5** is a longitudinal cross-sectional view of distal end **11** of the delivery system after sheath **16** has been withdrawn to expose stent **14**. FIGS. **6** and **7** show cross-sections of the delivery system wherein guide wire **12** is contained within the lumen of catheter **10** and the catheter is contained within a lumen of sheath **16**.

Referring again to FIG. **3**, guide catheter **38** has proximal and distal ends and is formed with a lumen for receiving the delivery assembly therein. The sheath **16**, with delivery catheter **10** slidably disposed in its lumen, extends through the lumen of the guide catheter. The guide catheter facilitates the advancement of the stent delivery system through a patient's vasculature and has a diameter large enough to allow free longitudinal movement of the stent deployment system therein. The stent **14** is located in the desired axial position within a body lumen. The position of the delivery catheter, which is carrying the stent, is set precisely relative to the position of the guide catheter, using means discussed in the above-referenced patent applications. This in turn enables precise deployment of the stent at the target site. The delivery sheath can be made of conventional polyethylene tubing, or engineering polymers such as nylon, PEEK (polyethylene ethyl ketone) or PET (polyethylene terephthalate).

Referring now to FIGS. **4**, **5**, **6** and **8**, at least a portion of delivery catheter **10** includes a first reinforcing element, such as coil **52**, connected thereto at a location proximal to stop **18**. The coil contains a plurality of windings **54**. The coil is fixedly attached to the delivery catheter in a fully longitudinally compressed condition with the windings positioned in apposition with each other. Consequently, the coil provides longitudinal compression resistance for the delivery catheter, while allowing for flexibility for navigation through a tortuous vasculature. The coil can be made of metal such as such as stainless steel, NITINOL® nickel-titanium alloy or any other suitable material. In one embodiment, the coil can extend longitudinally for 10 to 15 cm in the compressed condition.

In one embodiment, delivery catheter **10** can be a tube constructed from polyethylene ("PE tube") or other suitable materials. The coil **52** can be wound around the delivery catheter using a standard winding technique, known to those skilled in the art. At least a portion of the delivery catheter can include a second reinforcing element such as hypotube **50** or another elongated tubular member, connected thereto.

The hypotube is positioned over and attached to the delivery catheter using glue or other suitable means. The hypotube is positioned such that it is proximal to the coil. After the coil and the hypotube are positioned over the delivery catheter, they can be configured so that they are in apposition with each other. The proximal end of the coil could be placed over the distal end of the hypotube end welded thereto.

Once hypotube **50** and coil **52** are positioned over delivery catheter **10**, a heat-shrinkable tube can be placed over the device and then shrunk to secure the coil and hypotube to the delivery catheter. The hypotube provides further longitudinal compression resistance for the delivery catheter. The hypotube can be made of a rigid material such as metal. Preferably, the hypotube is made of stainless steel or NITINOL® nickel-titanium alloy for added kink resistance. As mentioned above, if the hypotube were used throughout the length of the catheter then the catheter may not have adequate flexibility. However, the coil fulfills at least two important functions. First, the coil will not compress longitudinally as it is already in a fully compressed condition. Second, the coil can bend, and therefore allows the catheter to bend. Thus, the coil provides added flexibility for navigation through a tortuous vasculature, while maintaining longitudinal compression resistance for the catheter.

Turning to FIG. **9**, in an alternate embodiment, the first reinforcing element can be made of a rigid material, such as plastic, in the shape of tube **60**. The tube can be made of polyimide or PEEK, in one embodiment. The tube **60** is fixedly attached to delivery catheter **10** at a location proximal to stop **18**. Consequently, tube **60** provides longitudinal compression resistance for the delivery catheter, while allowing for flexibility for navigation through a tortuous vasculature. In one embodiment, tube **60** can extend longitudinally for 10 to 15 cm.

In operation, guide catheter **38** is percutaneously introduced into the cardiovascular system of a patient through, for instance, the femoral artery, and is advanced therein until the distal tip thereof is just proximal of the vessel site to be treated. The stent deployment system is introduced through guide catheter **38** with guide wire **12** slidably disposed within the lumen of delivery catheter **10**. Upon reaching the distal end of the guide catheter, the guide wire is extended out from catheter **10** and is advanced to the target site. Thereafter, catheter **10** and stent **14** are advanced over guide wire **12**, such as by manipulating a manipulator handle or other appropriate device, until the stent is positioned at the desired location. The position of the stent mounted on the distal end of the delivery catheter is fixed relative to guide catheter **38**, as mentioned above, and therefore the two should remain stationary within the body lumen, even during stent deployment.

To deploy self-expanding stent **14**, the physician, while using a fluoroscope to view the treated site, withdraws sheath **16** proximally relative to both catheter **10** and self-expanding stent **14**. In the same motion that the sheath is withdrawn proximally, the stent is prevented from sliding proximally along catheter **10** by at least one immobile stop **18** located on the periphery of catheter **10**.

With sheath **16** withdrawn, self-expanding stent **14** is no longer restrained in a contracted state and expands against the vessel walls. After the stent has fully deployed, the delivery system is withdrawn from the patient's body with the stent remaining in the vessel lumen to maintain the patency of the treated vessel.

From the foregoing, it will be appreciated that the stent delivery system of the present invention allows self-expanding stents to be deployed while preventing any unwanted axial movement of the stent. The invention is made of materials commonly found in the industry and is simple to use and easy to manufacture.

While the invention herein has been illustrated and described in terms of a stent deployment system with a reinforced inner member, it will be apparent to those skilled in the art that the invention can be used in other instances. Other modifications and improvements may be made without departing from the scope of the invention.

What is claimed:

1. A stent deployment system for delivery of a self-expanding stent within a body lumen, comprising:

a delivery assembly including

an inner tubular member having a proximal end and a distal end, the distal end configured to receive over an exterior thereof the self-expanding stent;

wherein at least a portion of the inner tubular member includes a first reinforcing element connected thereto, the first reinforcing element providing longitudinal compression resistance for the inner tubular member, while allowing for flexibility for navigation through a tortuous vasculature; and

an elongated sheath having a proximal end and a distal end and formed with a lumen to slidably receive the inner tubular member; and

a guide catheter having a proximal end and a distal end, and formed with a lumen for receiving the delivery assembly therein.

2. The system of claim **1**, wherein the first reinforcing element is a coil.

3. The system of claim **2**, wherein the coil is fully compressed.

4. The system of claim **1**, wherein the first reinforcing element is made of metal.

5. The system of claim **1**, wherein the first reinforcing element is made of a rigid material in the shape of a tube.

6. The system of claim **5**, wherein the first reinforcing element is made of plastic.

7. The system of claim **1**, wherein the first reinforcing element adapted to be located proximal to the stent.

8. The system of claim **1**, wherein at least a portion of the inner tubular member includes a second reinforcing element connected thereto, the second reinforcing element providing longitudinal compression resistance for the inner tubular member.

9. The system of claim **8**, wherein the second reinforcing element is an elongated tubular member.

10. The system of claim **9**, wherein the second reinforcing element is positioned over and attached to the inner tubular member.

11. The system of claim **8**, wherein the second reinforcing element is made of a rigid material.

12. The system of claim **11**, wherein the second reinforcing element is made of metal.

13. The system of claim **8**, wherein the second reinforcing element is proximal to the first reinforcing element.

14. The system of claim **13**, wherein the second reinforcing element comes into apposition with the first reinforcing element.

15. The system of claim **1**, wherein the elongated sheath is formed with a cylindrical body of a first diameter and has an open-ended receptacle at the distal end for receiving the self-expanding stent;

and wherein the receptacle has a second diameter larger than the first diameter.

16. The system of claim **1**, wherein the inner tubular member further has an inner lumen adapted to receive a guide wire therethrough.

17. The system of claim 1, wherein a stop is disposed on an exterior of the inner tubular member adapted to be proximal to the self-expanding stent and distally to the first reinforcing element to prevent the stent from moving proximally during relative movement between the sheath and the inner tubular member.

18. The system of claim 17, wherein the stop includes an annular shape.

19. The system of claim 1, wherein the inner tubular member is a delivery catheter.

* * * * *

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(54) PROSTHESIS DEPLOYMENT DEVICE WITH TRANSLUCENT DISTAL END

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Related U.S. Application Data

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(60) Provisional application No. 60/134,267, filed on May 14, 1999.

Publication Classification

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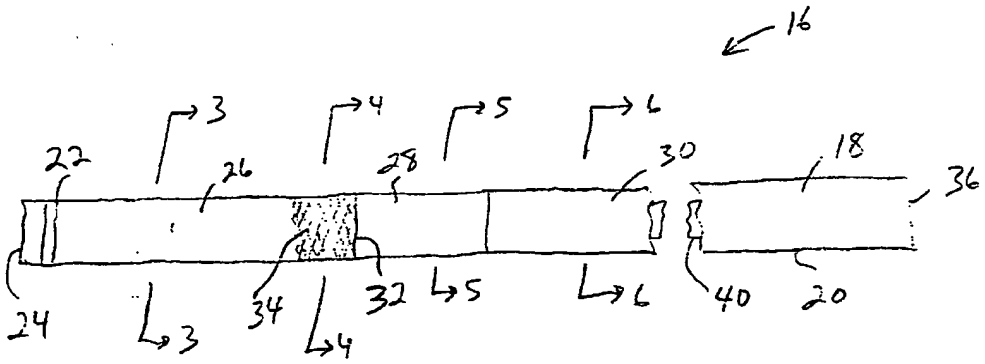
(52) **U.S. Cl.** **623/1.11**

(57) **ABSTRACT**

A prosthesis delivery and deployment device includes an elongate and flexible outer catheter. The outer catheter has a tubular wall of layered construction, including a translucent inner liner running the complete catheter length, and three outer layers including a translucent distal layer, an opaque medial layer and an opaque proximal outer layer. The outer layers are adjacent one another and are bonded to the liner. A braid composed of helically wound metal filaments is disposed between the liner and the proximal and medial outer layers, and includes a distal portion between the liner and a proximal portion of the distal outer layer. The liner and distal outer layer provide a translucent distal region of the catheter that is adapted to constrain a radially self-expanding prosthesis in a radially reduced, axially elongated state. Because the stent constraining region is translucent, an endoscope can be used to visually monitor the stent when so constrained. Radiopaque markers can be mounted to the outer catheter and to an inner catheter used to deploy the prosthesis, to afford a combined visual and fluoroscopic monitoring for enhanced accuracy in positioning the prosthesis, both before and during its deployment.



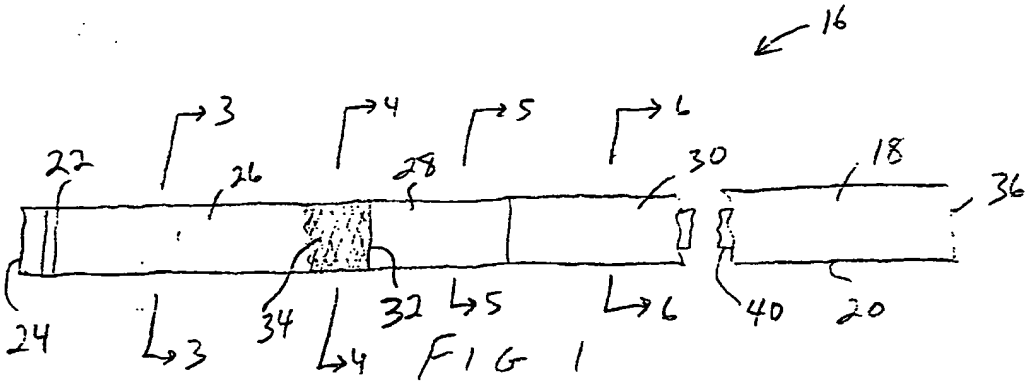


FIG 1

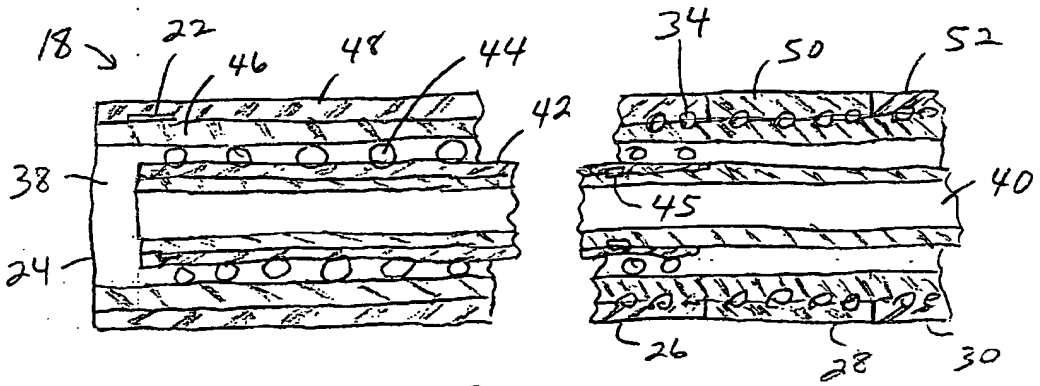


FIG 2

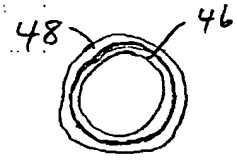


FIG 3

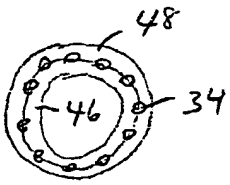


FIG 4

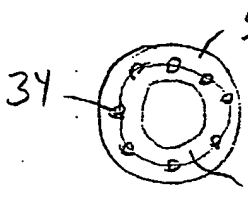


FIG 5

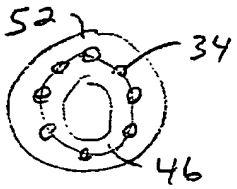


FIG 6

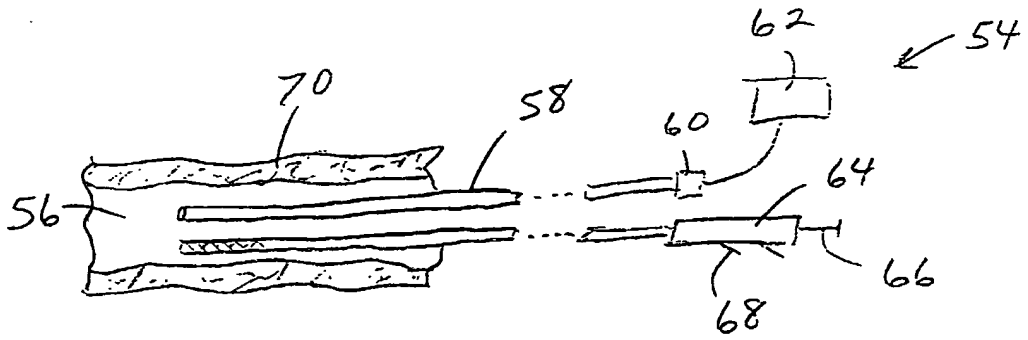


FIG 7

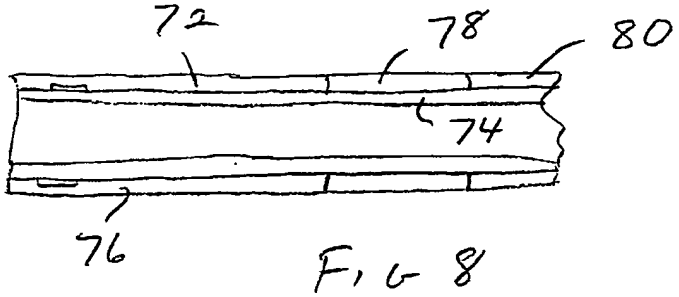


FIG 8

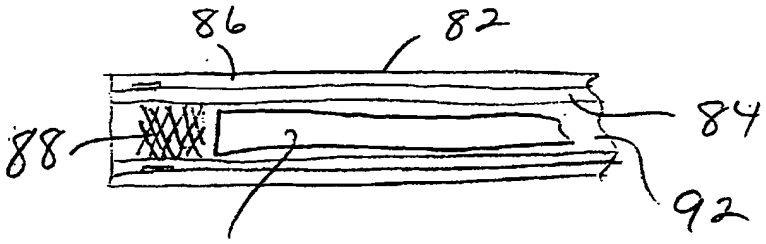


FIG 9

PROSTHESIS DEPLOYMENT DEVICE WITH TRANSLUCENT DISTAL END

[0001] This application claims the benefit of priority of Provisional Application No. 60/134,267 entitled "Translucent Medical Device," filed May 14, 1999.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to medical devices for delivering endoprostheses to predetermined treatment sites within body cavities or lumens, and further deploying the endoprostheses at the selected sites. More particularly, this invention relates to such devices that are capable of enabling or facilitating a tracking of the endoprostheses during deployment.

[0003] A variety of patient treatment and diagnostic procedures involve the use of prostheses inserted into the body of a patient and intraluminally implanted. Percutaneous translumenal coronary angioplasty (PTCA) and other vascular treatments frequently involve implanting prostheses such as stents to maintain vessel patency or grafts to shunt blood. Similar implantations are used in non-vascular procedures, e.g., enteral, billiary, and esophageal applications.

[0004] There is a need to accurately characterize the intended implant site to facilitate proper placement of the prosthesis. There is a further need, just before deployment and during deployment, to ascertain the location of the prosthesis relative to the intended placement site. One known approach to such characterizing and monitoring is angiography, which involves supplying a radiopaque contrast fluid to the cavity or lumen, then radiographically viewing the lumen. This approach, however, provides only a monochromatic, two-dimensional image showing a profile but no depth of field.

[0005] According to another approach, radiopaque markers can be placed on the delivery/deployment device. Before deployment, the position of the prosthesis within the device is known, and determining the device position in effect accurately determines the prosthesis position. This advantage is lost during deployment, however, and again the image offers neither distinctions in color nor depth of field.

[0006] According to yet another approach, the prosthesis can be fabricated at least in part using a radiopaque material. For example, the filaments of a stent can be formed of, or may incorporate a core formed of, platinum, tantalum or another radiopaque material. This approach likewise lacks the capacity for distinction among colors, and imposes limitations upon the materials used to form the prosthesis.

[0007] U.S. Pat. No. 5,411,016 discloses an intravascular balloon catheter having a lumen containing an angioscope. A distal portion of the catheter shaft, surrounded by the dilatation balloon, is transparent, and index markers are provided along the balloon. Thus, objects against which the balloon wall is pressed when the balloon is inflated can be quantified. This structure requires viewing the lumen through the catheter wall and the balloon wall, and does not address the need for monitoring the position of a prosthesis with respect to its delivery device during deployment. This need is particularly apparent in connection with radially self-expanding prostheses, which are constrained in radially reduced configurations during delivery, and must be released from their confining devices during deployment to permit radial self-expansion.

[0008] Therefore, it is an object of the present invention to provide a prosthesis delivery and deployment device that substantially surrounds a prosthesis to retain the prosthesis during delivery to a treatment site, yet facilitates an optical viewing of the prosthesis before and during its deployment.

[0009] Another object is to provide a prosthesis delivery device particularly well suited to negotiate tortuous intraluminal pathways in the body, that incorporates a translucent carrier segment through which a prosthesis carried within the device can be optically viewed.

[0010] A further object is to provide a process for deploying a radially self-expanding prosthesis within a body lumen in which an optical viewing device is advantageously used to view at least a proximal portion of the prosthesis to visually monitor a location of the prosthesis during its deployment.

[0011] Yet another object is to provide a catheter or other device for intraluminal delivery of a prosthesis, that incorporates a prosthesis confining wall sufficiently light transmissive to enable a viewing of the prosthesis through the wall, so that an optical instrument positioned within a body lumen outside the catheter can be used to observe the prosthesis contained in the delivery device, as well as tissue surrounding the delivery device.

SUMMARY OF THE INVENTION

[0012] To achieve these and other objects, there is provided a prosthesis delivery and viewing device. The device includes an elongate, flexible catheter having a tubular catheter wall defining a catheter lumen. The catheter, along a distal end region thereof, is adapted to substantially surround a body insertable prosthesis and thereby releasably retain the prosthesis within the catheter lumen. The catheter wall, at least along the distal end region, is translucent to allow an optical viewing of the body insertable prosthesis through the catheter wall when the prosthesis is so retained.

[0013] Most preferably, the distal end region of the wall is substantially transparent, i.e., highly transmissive of wavelengths in the visible spectrum. Satisfactory viewing is achieved, if the distal end region wall merely is translucent; more particularly, sufficiently light transmissive so that at least about 25% of light impinging directly upon one side of the catheter wall is transmitted through the wall to the other side. A polyether block amide, for example as sold under the brand name Pebax, has been found to be well suited as a catheter wall material, not only due to its relative transparency, but also because it provides a ductile or flexible catheter wall that bonds well with other polymeric material. Certain nylons also can be used, although they are not as ductile as the Pebax material.

[0014] The device is advantageously used as part of a system that also includes an optical viewing device positionable proximate the distal end of the catheter to facilitate an optical viewing of the prosthesis and surrounding body lumen or cavity. An endoscope is suitable as such a viewing device.

[0015] According to one particularly preferred construction, the catheter includes an elongate, flexible translucent inner tubular body. A flexible, translucent first outer tube surrounds and is integral with a distal end region of the inner tubular body. An elongate, flexible second outer tube sur-

rounds the inner tubular body, is integral with the inner tubular body, and is disposed proximally of the first outer tube. If desired, a flexible third outer tube is disposed between the first and second outer tubes, and contacts the other outer tubes to provide a substantially continuous profile composed of the three outer tubes. This construction allows a tailoring of the catheter, to provide a balance between two somewhat conflicting needs: sufficient flexibility to negotiate serpentine pathways; and sufficient columnar strength along the catheter length to provide the necessary axial pushing force.

[0016] In particular, such tailoring can involve selecting materials of different durometer hardness for the outer tubes. One highly preferred example uses a 63 Shore D durometer Pebax material in the first outer tube, and a 72 Shore D durometer Pebax material in the second, proximal outer tube which comprises most of the catheter length. To provide further columnar strength and resistance to kinking, a support structure can be interposed between the inner tubular layer and at least the second outer tube. A preferred structure is a braid of helically wound metal filaments, e.g., stainless steel or a cobalt-based alloy such as that sold under the brand name Elgiloy. If desired, the wire braid can extend distally beyond the second outer tube, and thus reside between the inner tubular layer and a proximal portion of the first outer tube, up to about one-half of the first outer tube length. When a third, medial outer tube is employed, it is preferably composed of a material having a 63 Shore D durometer hardness.

[0017] The delivery device further can include a prosthesis release component mounted moveably with respect to the catheter to effect a release of the prosthesis from within the catheter lumen. For example, an elongate flexible member, which can be a tube if desired, is disposed inside the catheter lumen and either abuts the proximal end of the prosthesis, or is surrounded by the prosthesis along its distal portion. In many cases the latter arrangement is more desirable, because it enables a retraction of the prosthesis after it is partially deployed, if repositioning is deemed necessary.

[0018] The delivery device is particularly well suited for use in a process for deploying a radially self-expanding prosthesis within a body lumen, including:

[0019] a. disposing a radially self-expanding prosthesis in a radially compressed state within a catheter, surrounded by a tubular wall of the catheter along a distal end region of the catheter;

[0020] b. moving the catheter intraluminally to position the distal end region of the catheter near a selected prosthesis deployment site within a body lumen;

[0021] c. with the catheter distal end region so positioned, initiating a release of the prosthesis from the catheter, and during the release, using an optical viewing device to optically view at least a proximal portion of the prosthesis through the catheter wall, to visually monitor a location of the prosthesis; and

[0022] d. after completing the release of the prosthesis, proximally withdrawing the catheter to leave the prosthesis disposed within the body lumen.

[0023] Thus in accordance with the present invention, a prosthesis can be optically viewed both before its release to insure an accurate positioning within a body lumen, and during its release to monitor its position both with respect to the lumen, and with respect to the delivery/deployment catheter. An endoscope or other suitable optical device can provide an image that enables the user to distinguish among colors, which can be beneficial in recognizing properties of the tissue at the treatment site. Optical images also afford depth of field. The capability of optically viewing the lumen and prosthesis when still contained within the catheter, combined with fluoroscopic imaging of the catheter and the prosthesis, provides particularly effective monitoring of the deployment and positioning of the prosthesis.

[0024] In the Drawings

[0025] For a further understanding of the above and other features and advantages, reference is made to the following detailed description and to the drawings, in which:

[0026] **FIG. 1** is a side elevation of a prosthesis delivery and deployment device constructed in accordance with the present invention;

[0027] **FIG. 2** is an enlarged elevation, partially sectioned to show further features of the device;

[0028] **FIGS. 3, 4, 5** and **6** are sectional views taken respectively along the lines **3-3, 4-4, 5-5**, and **6-6** in **FIG. 1**;

[0029] **FIG. 7** is a schematic view of a prosthesis deployment and viewing system incorporating the deployment device;

[0030] **FIG. 8** is a side elevation illustrating an alternative embodiment deployment device; and

[0031] **FIG. 9** is a side elevation illustrating another alternative embodiment deployment device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0032] Turning now to the drawings, there is shown a device **16** for delivering a radially self-expanding prosthesis to a selected treatment site within a body cavity or body lumen, and for deploying the prosthesis, once it is positioned at the treatment site. The device includes an elongate, flexible outer catheter **18** having a tubular catheter wall **20**. A radiopaque marker **22** is mounted to the catheter near its distal end **24**.

[0033] Along its axial length, catheter wall **20** is divided into three sections or regions: a distal region **26**; a medial region or transition region **28**; and a proximal region **30**. As indicated by the break, the full length of proximal region **30** is not shown in **FIG. 1**. The proximal region is by far the longest of the three regions. The diameter and axial length of catheter **18** can vary according to the application and size of the body lumen involved. Some typical ranges for enteral applications include a total catheter length of 135-230 cm in conjunction with a distal segment length of 7-18.5 cm, a transition region length of 6-7.5 cm, and a diameter of 5-22 French, i.e. about 1.7-3.0 mm.

[0034] Distal region **26** extends from distal end **24** to a junction **32** between two slightly different polymeric materials employed in forming the catheter wall. Along the distal region, the catheter wall preferably is transparent, exhibiting a high transmissivity of energy in the visible spectrum. Less preferably but satisfactorily, catheter wall **20** is translucent

along the distal region, in the sense that at least 25% of the energy in the visible spectrum impinging directly upon catheter **18** is transmitted through catheter wall **20** to the other side. A braid **34** formed of helically wound intersecting filaments of stainless steel, a cobalt-based alloy or other suitable metal, forms a layer of catheter wall **20** beginning at a distal region that is visible due to the transparency of the polymeric layer surrounding it. The braid extends proximally to a proximal end **36** of the catheter, provides a reinforcing structure that increases the columnar strength of medial region **28** and proximal region **30**, and also increases radial stability and resistance to kinking when catheter **18** is bent.

[0035] **FIG. 2** shows device **16**, particularly the distal and medial sections, in greater detail. Outer catheter **18** includes a catheter lumen **38** that runs substantially the entire catheter length. An inner catheter **40**, contained in lumen **38**, is movable axially relative to outer catheter **18**. Inner catheter **40** extends lengthwise substantially along the entire length of the outer catheter. A sleeve **42** surrounds inner catheter **40** along a distal portion of the catheter comparable to catheter distal region **26** in its axial length. A prosthesis, in particular a radially self-expanding stent **44**, surrounds the inner catheter and sleeve along the distal portion of the inner catheter. Stent **44** in turn is surrounded by the distal region of outer catheter **18**, constrained by the outer catheter wall in a radially reduced, axially elongated state. Stent **44** is radially self-expanding, in that once free of the outer catheter, the stent tends to shorten axially and expand radially to a normal or unstressed shape in which the stent diameter is much larger than the diameter of the outer catheter. Stent **44** is somewhat similar to braid **34**, in that the stent is composed of oppositely directed helically wound filaments or wires that intersect one another. However, because the filaments forming stent **44** typically are smaller in diameter than the filaments forming braid **34**, the filaments of the stent frequently are formed of materials selected for enhanced radiopacity, e.g. a composite construction including a tantalum core within an Elgiloy casing. A radiopaque marker **45** is located along inner catheter **40**, between the inner catheter and the sleeve.

[0036] The layered, segmented construction of catheter wall **20** is best seen in **FIG. 2**. Catheter wall **20** includes an inner layer, i.e. a PTFE liner **46** that extends for the length of the catheter. Liner **46** is substantially translucent to transparent, typically with an amber cast. Liner **46** typically is etched to improve bonding adhesion to the layers that surround it.

[0037] The surrounding layers, or outer tubes, include a transparent or translucent outer distal layer **48**, an opaque outer medial layer **50**, and an opaque outer proximal layer **52**. Marker **22** is disposed between liner **46** and distal outer layer **48**. Beginning near the proximal end of outer layer **48** and extending proximally for the remainder of the catheter length, braid **34** is interposed between outer layer **48**, medial outer layer **50** and proximal outer layer **52**. The outer layers are bonded to the liner. Consequently, the liner, outer layers, marker and braid are integral with one another.

[0038] In accordance with the present invention, materials are selected for the liner and outer layers to impart desired properties that differ over the length of catheter **18**. As noted above, liner **46** is formed of PTFE. The inside surface of liner **46** preferably is coated with silicone, to provide a low-friction surface to contact stent **44** and facilitate axial travel of inner catheter **40** relative to the outer catheter. Liner **46** is cylindrical, and can have for example an inner diameter of 0.117 inches and a radial thickness of 0.0015 inches.

[0039] Over the majority of the catheter length, the next radially outward layer is composed of braid **34**. The filaments of braid **34** can be stainless steel wires, having a diameter of about 0.015 inches. In one advantageous arrangement, **32** wires are wound helically, interbraided in a two-over-two-under pattern, at about 52 pics per inch. The braid angle can be 110-150 degrees, i.e. 55-75 degree inclines from a longitudinal axis.

[0040] At the distal end of catheter **18**, radiopaque marker **22** is provided in the form of an annular band surrounding liner **46**. The band can be formed of a platinum/iridium alloy, and can have a diameter of 0.127 inches and radial thickness of about 0.0015 inches.

[0041] Distal outer layer **48** surrounds and is bonded to liner **46**. The preferred material for the distal outer layer is a polyether block amide available under the brand name "Pebax," with a 63 Shore D durometer hardness. Outer layer **48** is substantially transparent. Accordingly, liner **46** and outer layer **48** in combination provide a catheter wall region that is substantially transparent, or at least sufficiently translucent so that stent **44**, when contained within catheter **18** as shown in **FIG. 2**, is visible from outside the catheter through the catheter wall. Another favorable property of outer layer **48** is its relatively high flexibility, whereby the distal region is well suited for initial tracking through serpentine body passages as the catheter is moved toward an intended treatment site. Distal outer layer **48** can have a diameter of about 1.17 inches, and a thickness of about 0.010 inches.

[0042] Medial outer layer **50** also is preferably constructed of the Pebax polyether block amide, having the same 63 Shore D durometer hardness. The polymer is combined with a blue dye, and thus forms an opaque layer. Outer layer **50** can have an axial length of about 5 cm, an inner diameter of about 0.129 inches, and a radial thickness of about 0.012 inches. Due to the contrast between the translucent outer layer **48** and the opaque outer layer **50**, junction **32** provides a clear visible marker that locates the proximal end of stent **44** when the stent is radially constrained by the outer catheter.

[0043] Transition region **28** includes the full length of outer layer **50**, and in addition the length of braid **34** extending distally into distal region **26**. Although the visible distal extension of the braid can include half the length of distal region **26** and even more if desired, this extension typically is in the range of 1-2.5 cm. The transition region thus combines braid **34** and the 63 D durometer hardness Pebax polymer, with part of the polymer being translucent and part being opaque. Transition region **28** is flexible, although less flexible than the distal region. The braid reduces kink potential.

[0044] Proximal outer layer **52** is formed of a Pebax polymer having a 72 Shore D durometer hardness. The proximal outer layer can have an inner diameter of 0.129 inches and a radial thickness of 0.012 inches, same as the medial outer layer. Also like the medial layer, proximal outer layer **52** is combined with a blue dye to render this region of

the catheter opaque. The higher durometer hardness of the proximal outer layer provides enhanced column strength, thus to provide the axial pushing force necessary for advancing the catheter distally through body passages.

[0045] Less highly preferred but satisfactory results may be achieved when forming the various catheter wall components using alternative materials. For example, several grades of nylon including nylon **12** may be used to form outer layers **48**, **50** and **52**. A suitable alternative material for liner **46** is polyurethane, e.g. as available under the brand name Pellethane. A nylon available under the brand name Arnitel is suitable for the outer layers, although better suited for the opaque outer layers than translucent outer layer **48**.

[0046] Inner catheter **40** is preferably formed of polyether ether ketone (PEEK). The polymer forming sleeve **42** preferably is substantially softer and more flexible than the other polymers, so that stent **44** when disposed between the catheters as shown in **FIG. 2** tends to embed itself into the sleeve.

[0047] **FIG. 7** illustrates a system **54**, including device **16**, for delivering and deploying stent **44** within a body lumen **56**. The system includes an endoscope **58** positionable within body lumen **56** proximate distal region **26** of the catheter. Although the endoscope is represented schematically, it is to be understood that the endoscope can incorporate a light source **60**, an optical fiber or other suitable optical path to transmit light to the distal end of the endoscope, an optical fiber, bundle of fibers or other suitable path to transmit images proximally along the endoscope, and a display terminal **62** for displaying the visible image. The proximal end of outer catheter **18** is coupled to a manifold **64**. A handle **66**, coupled to inner catheter **40** and movable relative to the manifold, controls axial movement of the inner catheter relative to the outer catheter. Additional fittings **68** are provided for a variety of purposes depending on the procedure, potentially including accommodating a guidewire, transmitting a therapeutic drug to the distal end of the catheter, and accommodating a balloon inflation fluid for a dilatation balloon.

[0048] System **54** is used in a stent implant procedure as follows. First, a guidewire or guide canula is used to track endoscope **58** to the selected implant site. Likewise, a guidewire (not shown) is tracked to the site.

[0049] Next, device **16** is loaded onto the guidewire and tracked to the site. The flexibility of the distal section improves cornering through the body passages on the way to the site. Meanwhile, proximal region **30** provides the column strength necessary to push the device toward the site. Braid **34** provides resistance to kinking, combined with the ability to track tight radii.

[0050] As distal end **24** of the device approaches the treatment site, junction **32** between translucent and opaque regions provides a reliable visible indication to locate the proximal end of the constrained stent **44**.

[0051] Once the catheter distal end is positioned as desired, stent **44** is deployed, by pulling outer catheter **18** proximally while controlling handle **66** to maintain inner catheter **40** in place. Due to the softness of sleeve **42** and the lubricity of silicone coated liner **46**, stent **44** tends to remain with the inner catheter rather than moving proximally with the outer catheter.

[0052] As the outer catheter continues to move proximally, distal end **24** is carried proximally with respect to the distal end of the stent, thus partially freeing the stent for radial self-expansion. Because of the translucency of the outer catheter wall along distal end region **26**, endoscope **58** can be used continuously during deployment to monitor the position of stent **44**, relative to body lumen **56** and relative to inner catheter **40**. Moreover, as outer catheter **18** continues to move axially relative to inner catheter **40**, radiopaque marker **22** likewise moves axially relative to marker **45**, thus to permit a fluoroscopic monitoring of the outer catheter axial position relative to the inner catheter. Markers **22** and **45** can be positioned such that as marker **22** approaches marker **45**, a limit approaches beyond which deployment cannot be reversed, i.e. when the stent no longer can be drawn back into outer catheter **18** by advancing the outer catheter distally relative to the inner catheter. The combined visual and fluoroscopic monitoring enables the user to more precisely confirm an appropriate positioning of the stent before exceeding the limit.

[0053] Beyond the limit, outer catheter **18** is moved proximately until stent **44** is completely free of the outer catheter. This leaves the stent free to radially self-expand to its nominal diameter. The nominal diameter typically exceeds a diameter of body lumen **56**, so that the stent self-expands into an intimate contact with a tissue wall **70** defining the body lumen. With the implant of the stent thus complete, endoscope **58** and device **16** are proximally withdrawn, leaving the stent implanted at the treatment site.

[0054] **FIG. 8** illustrates a portion of an alternative embodiment outer catheter **72** including a single liner **74** and several outer layers including a distal outer layer **76**, medial outer layer **78** and proximal outer layer **80** as before. Outer catheter **72** differs from outer catheter **18**, in that all three of the outer layers are translucent or substantially transparent, providing an outer catheter that is translucent or substantially transparent over its entire length.

[0055] **FIG. 9** illustrates an outer catheter **82** of another alternative embodiment device, including an inner liner **84** and a single outer layer **86** running substantially the entire outer catheter length. A body implantable stent **88** is constrained along the distal region of the outer catheter, in a radially reduced axially elongated state. An inner catheter **90** is contained within a lumen **92** of the outer catheter. Rather than being surrounded by the stent, inner catheter **90** is disposed proximally of the stent, and movable distally relative to the outer catheter to engage the proximal end of the stent. Catheter **90** deploys the stent by pushing the stent distally relative to catheter **82**. While this approach is suitable for certain procedures, and may reduce the cost of the device, it also lacks the capability of reversing stent deployment to reposition the stent.

[0056] Thus, in accordance with the present invention, a prosthesis can be visually monitored during its deployment, even when substantially or entirely contained within the deployment catheter. When provided with layers of differing flexibility over the catheter length, the catheter can be sufficiently flexible at its distal end for efficient tracking, yet sufficiently rigid along its more proximal regions to insure adequate distal pushing force. Further, radiopaque markers can be employed to enable fluoroscopic monitoring of device components as well as visual monitoring of the

device and stent, to insure that the stent not only is properly aligned at the outset of deployment, but remains in the desired position as it is released from the deployment device.

What is claimed is:

1. A prosthesis delivery and viewing device, including:

an elongate, flexible catheter having a tubular catheter wall defining a catheter lumen, said catheter body along a distal end region thereof being adapted to substantially surround a body insertable prosthesis and thereby releasably retain the prosthesis within the catheter lumen;

wherein the catheter wall, at least along the distal end region, is translucent to allow an optical viewing of the body insertable prosthesis through the catheter wall when the prosthesis is so retained.

2. The device of claim 1 further including:

a prosthesis release component mounted movably with respect to the catheter to effect a release of the prosthesis from within the catheter lumen.

3. The device of claim 2 wherein:

the prosthesis release component includes an elongate, flexible member disposed inside the catheter lumen and adapted to move the prosthesis distally relative to the catheter to effect the release.

4. The device of claim 3 wherein:

a distal end of the flexible member is disposed proximally of the prosthesis when the prosthesis is so retained.

5. The device of claim 3 wherein:

the flexible member has a distal end portion surrounded by the prosthesis when the prosthesis is so retained.

6. The device of claim 1 wherein:

the prosthesis is radially self-expanding, and when so retained is confined in a radially compressed state.

7. The prosthesis of claim 1 further including:

an optical viewing device positionable proximate the distal end of the catheter to facilitate said optical viewing.

8. The device of claim 1 wherein:

the catheter wall is more flexible along the distal end region as compared to a remaining portion of the catheter disposed proximally of the distal end region.

9. The device of claim 1 wherein:

the catheter wall is translucent substantially over an entire length of the catheter.

10. The device of claim 1 wherein:

a remaining portion of the catheter disposed proximally of the distal end region is opaque.

11. The device of claim 1 further including:

a metal reinforcing structure integral with the catheter wall, at least along a remaining portion of the catheter wall disposed proximally of the distal end region.

12. The device of claim 1 wherein:

the catheter wall includes a translucent inner tubular layer, a translucent first outer tubular layer surrounding the inner tubular layer along a distal end portion of the inner tubular layer, and a second outer tubular layer surrounding the inner tubular layer and disposed proximally of the first outer tubular layer.

13. The device of claim 12 wherein:

the second outer tubular layer is opaque.

14. The device of claim 12 wherein:

the first outer tubular layer is more flexible than the second outer tubular layer.

15. The device of claim 12 further including:

a radiopaque marker disposed near a distal end of the catheter wall and between the inner tubular layer and the first outer tubular layer.

16. The device of claim 12 further including:

a metal reinforcing structure disposed between the inner tubular layer and the second outer tubular layer.

17. The device of claim 16 wherein:

the metallic reinforcing structure includes a plurality of helically wound and interbraided filaments.

18. A catheter for deploying a body insertable prosthesis, including:

an elongate, flexible, translucent inner tubular body;

a flexible, translucent first outer tube surrounding and integral with a distal end region of the inner tubular body; and

an elongate, flexible second outer tube surrounding the inner tubular body, integral with the inner tubular body, and disposed proximally of the first outer tube.

19. The catheter of claim 18 further including:

a flexible third outer tube disposed between, and in contact with, the first outer tube and the second outer tube.

20. The catheter of claim 18 wherein:

the second outer tube is opaque.

21. The catheter of claim 18 further including:

a radiopaque marker disposed between the inner tubular body and the first outer tube, and further disposed proximate respective distal ends of the inner tubular body and the first outer tube.

22. The catheter of claim 18 including:

a reinforcing structure disposed between the inner tubular body and the second outer tube.

23. The catheter of claim 22 wherein:

said reinforcing structure further is disposed between the inner tubular body and a proximal portion of the first outer tube.

24. The catheter of claim 22 wherein:

the reinforcing structure comprises helically wound metal filaments interbraided with one another.

25. The catheter of claim 18 wherein:

the first outer tube is more flexible than the second outer tube.

26. The catheter of claim 18 further including:

a radially self-expanding prosthesis disposed within the inner tubular body, in substantial axial alignment with the first outer tube, and constrained in a radially compressed state.

27. The catheter of claim 18 further including:

a prosthesis release component mounted movably relative to the inner tubular body.

28. The device of claim 27 wherein:

the prosthesis release component includes an elongate, flexible member contained inside the inner tubular body.

29. A process for deploying a radially self-expanding prosthesis within a body lumen, including:

disposing a radially self-expanding prosthesis in a radially compressed state within a catheter, surrounded by a tubular wall of the catheter along a distal end region of the catheter;

moving the catheter intraluminally to position the distal end region of the catheter near a selected prosthesis deployment site within a body lumen;

with the catheter distal end region so positioned, initiating a release of the prosthesis from the catheter, and during said release, using an optical viewing device to optically view at least a proximal portion of the prosthesis through the catheter wall, to visually monitor a location of the prosthesis; and

after completing the release of the prosthesis, proximally withdrawing the catheter to leave the prosthesis disposed within the body lumen.

30. The process of claim 29 wherein:

the initiating of the release of the prosthesis comprises positioning an elongate prosthesis release member in contact with the prosthesis, and moving the tubular catheter proximally while using the release member to substantially prevent the prosthesis from moving proximally with the catheter.

31. The process of claim 30 further including:

while visually monitoring a location of the prosthesis, further monitoring a position of the elongate prosthesis release member relative to the catheter.

32. The process of claim 29 further including:

before initiating a release of the prosthesis, using a visible indicium on the tubular catheter to approximate a location of the proximal portion of the prosthesis with respect to the body lumen.

33. A prosthesis delivery and deployment catheter, including:

an elongate, flexible inner tubular body;

a flexible first outer tube surrounding and integral with a distal end region of the inner tubular body; and

an elongate, flexible second outer tube surrounding the inner tubular body, integral with the inner tubular body, and disposed proximally of the first outer tube;

wherein the first outer tube is more flexible than the second outer tube, and extends axially less than one-fourth of the length of the inner tubular body, and wherein the second outer tube extends axially at least three-fourths of the length of the inner tubular body.

34. The catheter of claim 33 wherein:

the second outer tube has a durometer hardness greater than that of the first outer tube.

35. The catheter of claim 33 further including:

a flexible third outer tube disposed between, and in contact with, the first outer tube and the second outer tube.

36. The catheter of claim 35 wherein:

the second outer tube and the third outer tube are opaque, and the inner tubular body and the first outer tubing are translucent.

* * * * *

US005817101A

United States Patent [19]

Fiedler

[11] Patent Number: 5,817,101

[45] Date of Patent: Oct. 6, 1998

[54] **FLUID ACTUATED STENT DELIVERY SYSTEM**

[75] Inventor: **Gary R. Fiedler**, Plymouth, Minn.

[73] Assignee: **Schneider (USA) Inc**, Plymouth, Minn.

[21] Appl. No.: **816,077**

[22] Filed: **Mar. 13, 1997**

[51] **Int. Cl.**[6] **A61F 11/00**; A61M 29/00

[52] **U.S. Cl.** **606/108**; 606/191

[58] **Field of Search** 606/1, 108, 191–200

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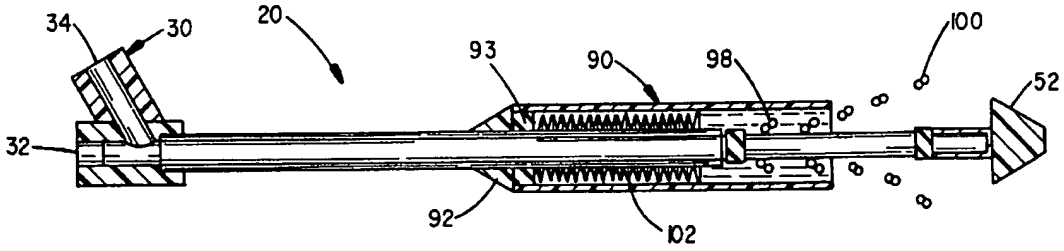
Primary Examiner—Glenn K. Dawson

Attorney, Agent, or Firm—Haugen and Nikolai, P.A.

[57] **ABSTRACT**

A delivery system for procuring implantation of an expandable stent into a bodily lumen of interest is disclosed including a fluid-operated moving cylinder sleeve for retaining the stent in place during delivery. The sleeve to release a stent at the implantation site. A fluid driven bellows may be employed to retract the sleeve.

11 Claims, 5 Drawing Sheets



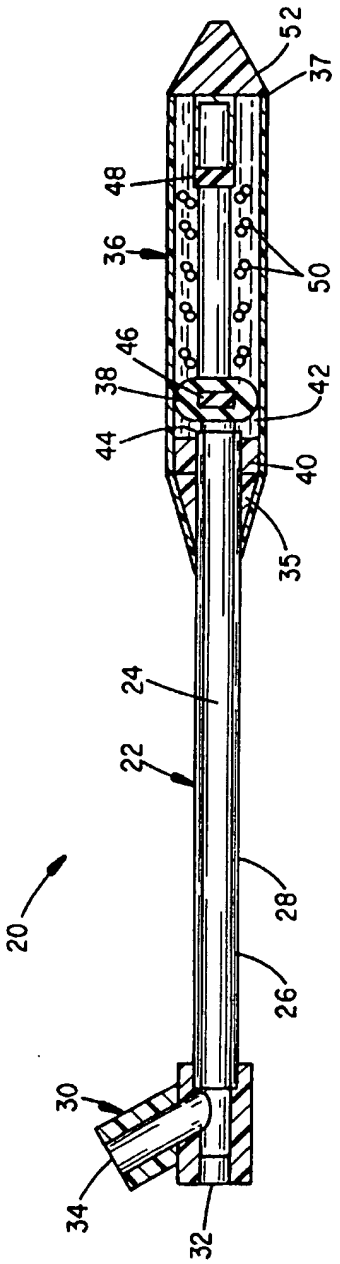

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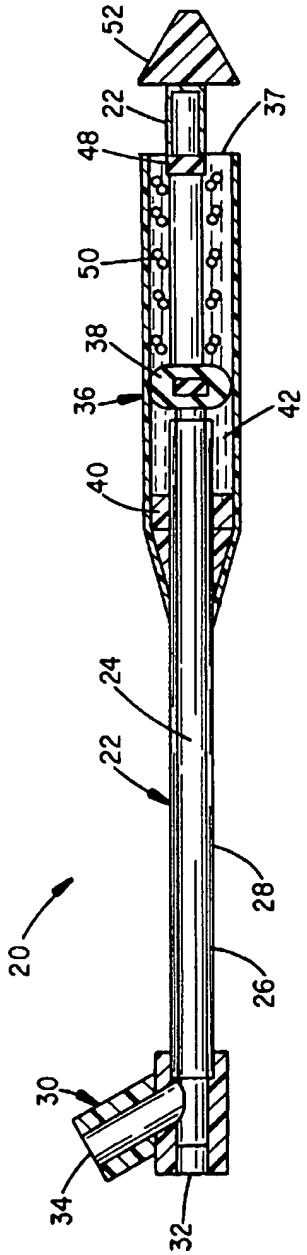
FIG. 1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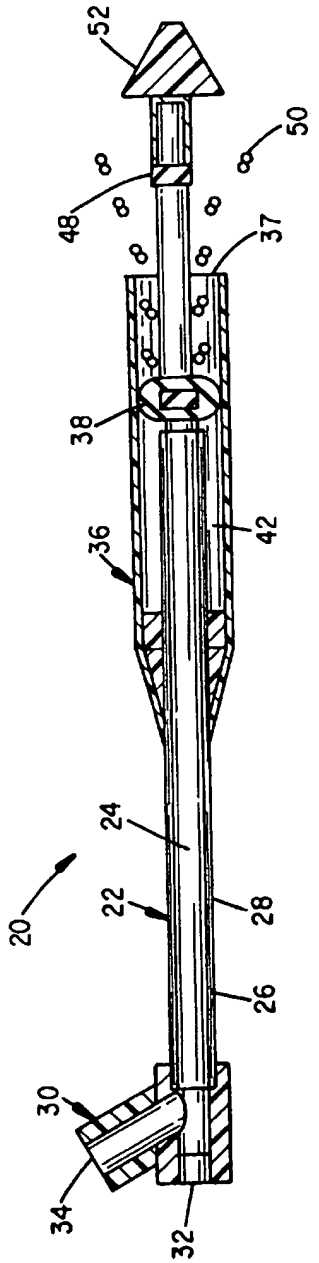
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FIG. 3

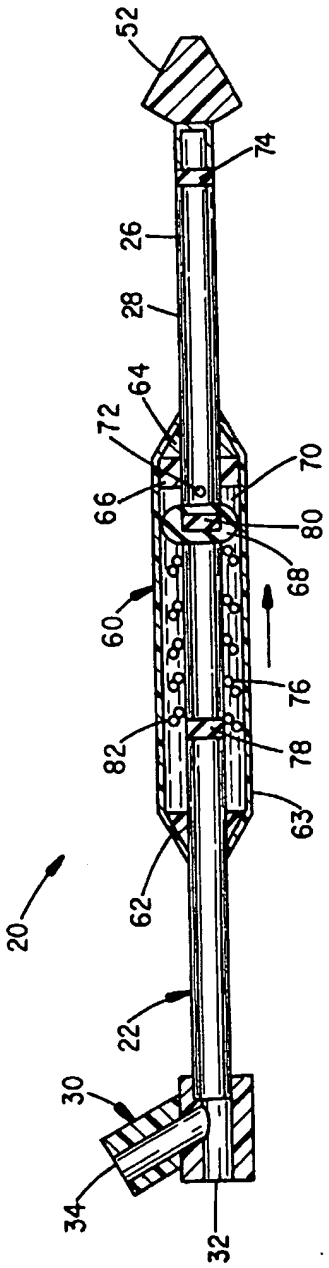
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FIG. 4

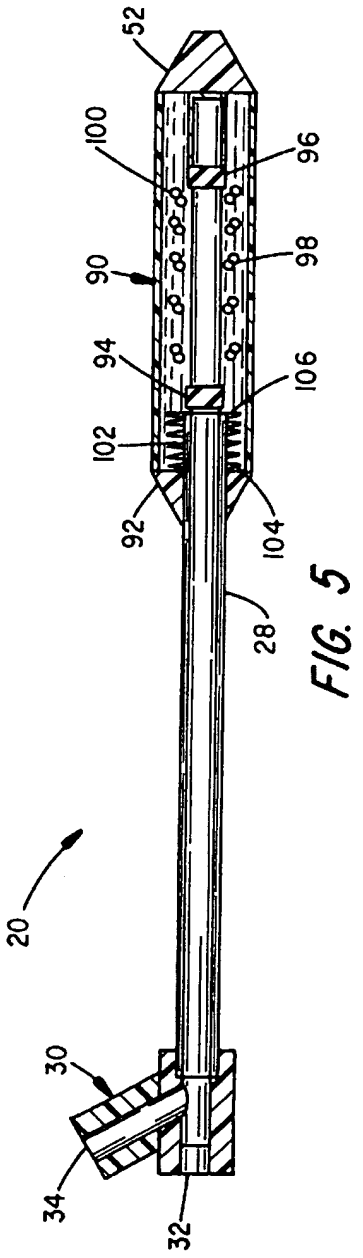
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FIG. 5

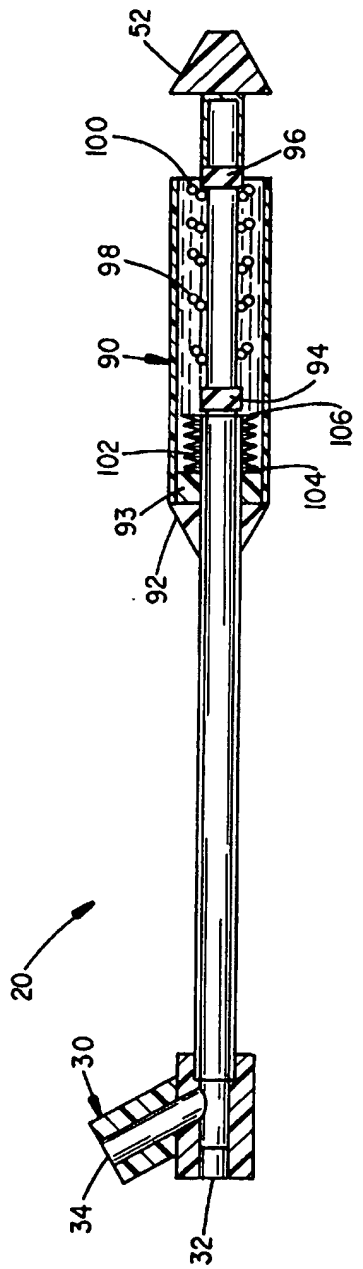
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FIG. 6

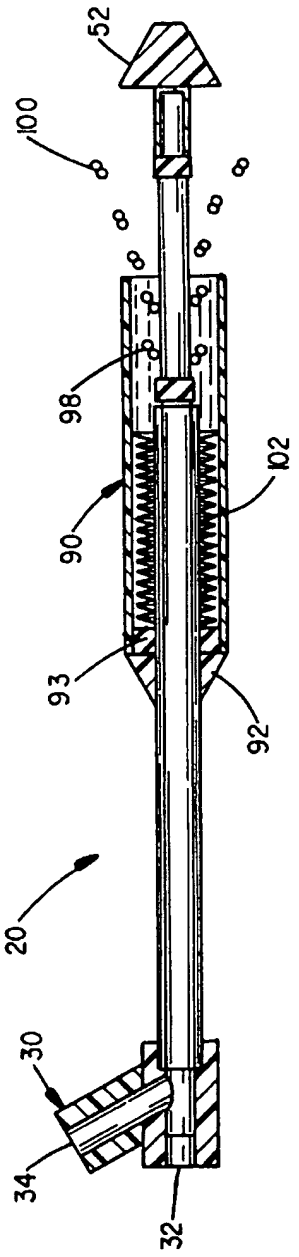
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FIG. 7

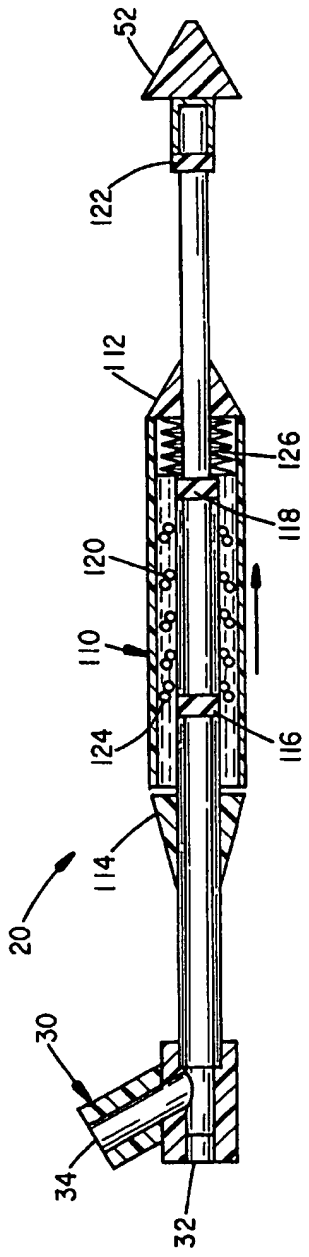
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FIG. 8

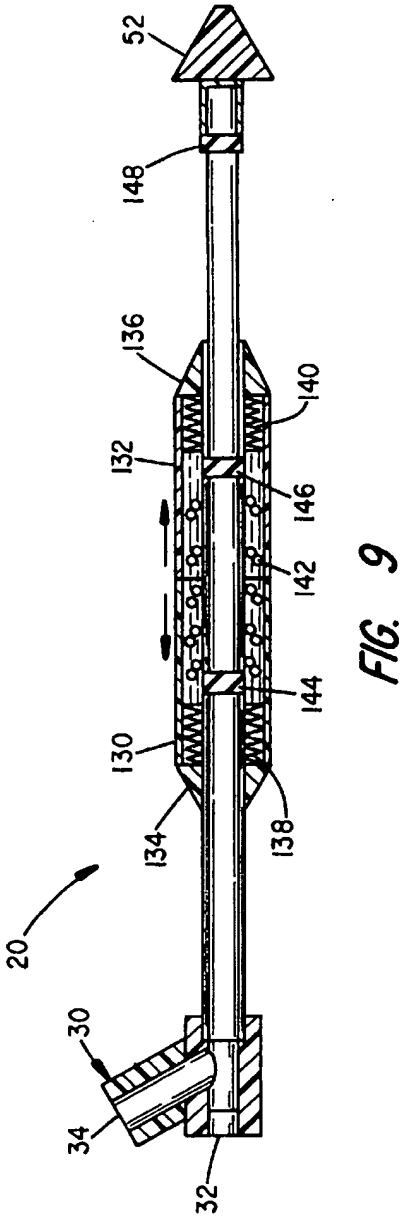

FIG. 9

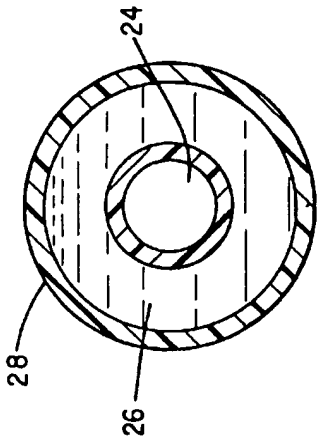

FIG. 11

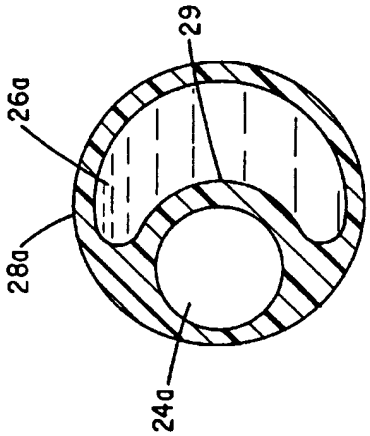

FIG. 10

FLUID ACTUATED STENT DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to the implantation of stent prostheses in body lumens and to delivery systems for transporting and accurately deploying or releasing such stents. More specifically, the invention is directed to a mechanism method for delivering and deploying a self-expanding stent utilizing a fluid-operated containment and releasing system.

II. Related Art

Auxiliary to surgical or other related invasive medicinal procedures, expandable stent implant devices are widely used in blood vessels, urinary tract ducts or other difficult to access places for the purpose of preventing restenosis, providing temporary or permanent vessel or lumen wall support or reinforcement and for other therapeutic or restorative functions. These devices are generally cylindrical or tubular in shape and are conveyed to a predetermined site or location of interest utilizing a vascular catheter, or similar transluminal device. In order to navigate the vascular system, the stents are delivered to the site constrained in a collapsed configuration or state of reduced diameter and are thereafter deployed by being released to expand or be expanded in situ. While temporary uses exist, these devices are generally designed as permanent implants which may become incorporated in the vascular or other tissue which they contact at implantation.

The stents are generally self-expanding or otherwise expanded in situ utilizing a fluid balloon or other such device. While the delivery and deployment system of the present invention can be adapted for use with either type of stent, the detailed embodiments illustrate deployment of the self-expanding variety. One well-known example of a type of self-expanding stent has become known as the Wallsten stent and is further illustrated and described in several issued U.S. patents, including Wallsten (U.S. Pat. No. 4,954,126); Wallsten (U.S. Pat. No. 4,655,771); and Wallsten et al (U.S. Pat. No. 5,061,275). (All documents cited herein, including the foregoing, are incorporated herein in their entirety for all purposes.) The Wallsten device is a woven device which has a flexible body formed of several individual flexible thread elements, each of which extends in a helix configuration with the center line of the body serving as a common axis. The elements are wound in the common direction but are displaced axially relative to each other and, under crossing a like number of elements also so axially displaced, but having the opposite direction of winding. This configuration provides a resilient braided tubular structure which assumes stable dimensions upon relaxation, but which elongates under axial tension with corresponding diameter contraction thereby enabling the stent to be mounted on a relatively small diameter catheter device and conveyed through the vascular system in a collapsed state or reduced diameter elongated configuration. As used herein, "stent" includes stent-graft and coated stents known in the art.

As indicated above, the delivery of these devices is generally accomplished by catheters of a class capable of delivering the stent to the site of interest, generally through the vascular system of the patient. Since this normally requires time consuming, torturous navigation to remote locations, improvements in the ability to accurately and easily deploy such stents once the site is reached are highly desirable.

Systems have been developed for remotely releasing the stents once the location of interest has been reached. One such system is illustrated and described in Euteneuer et al (U.S. Pat. No. 5,445,646) in which a delivery system for implantation of a self-expanding stent is disclosed which utilizes a retractable slipping sleeve system to expose a self-expanding stent held in a constrained position by bodily fluid-soluble retaining means which dissolve or swell to release the stent to radial expansion. The sleeves may be fluid operated.

While prior stent delivery systems have met with a degree of success, there remains a need for a system that will rapidly and accurately deploy a stent using distal, medial or proximal deployment. Using these terms, deployment or release is categorized according to the portion of the stent first released or expanded in situ. Delays necessitated by waiting for dissolution or expansion of retaining bands or other such constraint means require additional time which may allow unavoidable or undesirable movement of the stent, thereby reducing placement accuracy. Waiting for a delayed release system also extends the time required for the procedure.

Accordingly, it is highly desirable to provide a stent delivery system of the class described which increases the accuracy and reduces the time required for stent deployment and which, at the same time, makes the procedure easier for the operator and reduces the time required for the procedure.

It is a primary object of the present invention to provide a stent delivery and deployment system that permits rapid remote release of a stent in the location of interest.

Another object of the present invention is to provide an improved stent delivery and deployment system in which retractable deployment means also serves as the constraint means for the stent during transportation to the site of interest.

Yet another object of the present invention is to provide an improved stent delivery and deployment system which utilizes a self-retracting, extendable, improved fluid-operated release system.

Yet still another object of the present invention is to provide an improved stent delivery and deployment system which utilizes a collapsing bellows to operate the retracting device that serves as both constraint and deployment means.

Other objects and advantages of the present invention will occur to those skilled in the art upon familiarization with the descriptions and accounts contained in the specification.

SUMMARY OF THE INVENTION

By means of the present invention, there is provided a stent delivery and deployment system for procuring implantation of an expandable stent in a bodily lumen of interest. The catheter delivery and deployment system includes an elongate flexible catheter device designed to navigate the vascular system of a patient and to carry a stent retaining and deployment device attached toward the distal end of the catheter for deploying and expanding an expandable stent device, or possibly a stent-graft. The deployment system utilizes a fluid/operated retractable tubular sleeve system first as a containment or constraint device for initially retaining the stent on the catheter beneath the sleeve in a collapsed delivery configuration prior to release. Once properly aligned in situ, the tubular sleeve system is operable to retract from over the stent to release the stent distally, proximally or medially according to design of the system. In this manner, the stent can be positioned with accuracy; and at the beginning of release, should it be necessary, the stent can generally also be repositioned in the lumen.

In the detailed embodiments illustrating the invention, the catheter includes inner and outer co-axial tube members describing co-axial lumens and a constraint/release sleeve having a closed end slidably sealed about the outer co-axial tube and an open end through which a stent is released. The catheter connects proximally with a guidewire port and a fluid infusion port such that the inner co-axial lumen is a guidewire lumen and the outer lumen provides a fluid infusion lumen surrounding the inner tube.

In one embodiment, a first seal, or sliding seal, that is slidable along the outer catheter tube with respect to the sleeve is provided at the closed end of the sleeve sealing the inside of the sleeve to the outer catheter tube. A second seal, or stationary seal, that is stationary with respect to the catheter tubes, but slidable within the sleeve, is provided spaced from the first or sliding seal sealing the tube to the catheter and with the first seal defining a closed volume therebetween. The stent device is constrained by the sleeve portion extending beyond the stationary seal. Pressurized fluid infused from the outer lumen into the closed volume causes the volume to extend and the sleeve with the sliding seal to move away from the stationary seal and the stent thereby exposing and releasing the stent from the open end. The outer catheter tube may have infusion ports between the seals or it may end within the closed volume opening the lumen into the volume.

In an alternate embodiment, the outer catheter tube is connected to infuse into one or more extendable sealed bellows devices having one end which extends against a stop in the direction of the open end of the sleeve to urge the closed end of the sleeve in the opposite direction. As in the previous embodiments, the bellows can be configured to retract or collapse when the extended fluid pressure is released to urge the sleeve toward its original position in the manner of a double acting system.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings wherein like numerals depict like parts throughout the same.

FIG. **1** depicts schematically a catheter stent delivery and deployment device in accordance with the invention, partially in section, including a fluid operated single retractable sleeve for distal release shown in the fully closed or stent retention or stent delivery disposition;

FIG. **2** depicts the device of FIG. **1**, slightly reduced, at the beginning of the deployment or release cycle with the sleeve slightly retracted;

FIG. **3** depicts the device of FIG. **2** with the sleeve retracted to a larger degree and the stent partially released;

FIG. **4** depicts an alternate embodiment of the device of FIG. **1** in which the fluid operated sleeve is arranged for proximal stent deployment;

FIG. **5** depicts an alternate embodiment of the fluid operated delivery and deployment device of FIG. **1** in which the sleeve is operated by a fluid operated extendable bellows;

FIG. **6** depicts the device of FIG. **5**, slightly reduced, at the beginning of the deployment or release cycle with the sleeve slightly retracted;

FIG. **7** depicts the device of FIG. **6** with the sleeve further retracted and the stent partially released;

FIG. **8** depicts an alternative embodiment of the device of FIG. **5** in which the sleeve is arranged for proximal deployment of the stent; and

FIG. **9** illustrates an alternate embodiment for medial deployment of the stent utilizing a pair of oppositely disposed retractable tubular sleeve members.

FIGS. **10** and **11** are crossectional views illustrating bi-lumen and co-axial catheter construction.

DETAILED DESCRIPTION

The stent delivery and deployment system of the invention is portrayed by the several detailed embodiments which are included but which, it should be noted, are intended as examples rather than as definitive of the limitations of the scope of the invention. The system employs a retractable constraint in the form of an outer tubular sleeve or sleeves designed to perform a dual function. They are configured to retain a stent in a condition of reduced diameter otherwise defined as a delivery configuration which is required during storage and during transport or navigation through the vascular system of the patient and thereafter to axially retract from over the stent to release the stent at an implant site. With the system of the invention, a stent can be placed in situ, distal end first (distally); proximal end first (proximally); or by initially releasing and deploying the central section of the stent (medially). The deployment sleeve system can be operated as a single acting fluid actuated retractable device in which a portion of the sleeve operates with seals as an extending cylinder. In the alternative, the system can be operated using a double acting, (self-collapsing) fluid-extending bellows arrangement in which the bellows operates to retract the sleeve and release the stent and thereafter collapses to reclose the system.

FIGS. **1–3** illustrate a fluid-operated delivery and deployment catheter system generally at **20** for distally releasing a stent. The system includes an elongated central or primary catheter tube **22** which, it will be recognized, is relatively much longer than represented in the schematic figures. The tube **22** describes a continuous internal guidewire lumen **24** extending the length of the catheter and is itself co-axially nested inside a continuous fluid supply or fluid lumen **26** of an outer or secondary catheter tube **28** for much of its length. The proximal portion of this co-axial tube system is further mounted within a valve body, generally, **30** which contains a guidewire port **32** which connects with primary or guidewire lumen **24**. A hydraulic (normally saline) fluid infusion port **34** is provided in the valve body **30** that connects secondary tube fluid lumen **26** with a source of and drain for pressurized fluid for extending and collapsing a fluid-operated deployment system.

FIG. **11** illustrates in greatly magnified crossection the co-axial construction described. FIG. **10** shows an alternate positioning of the two lumens in what is known as a bi-lumen or side-by-side configuration in which the guidewire lumen **24***a* and the fluid lumen **26***a* are contained within the catheter tube **28***a* separated by an internal wall **29**. It will be recognized that the description regarding the co-axial arrangement contained herein apply equally to a bi-lumen arrangement as well. The two arrangements are believed close enough to each other in construction that a repetition of the entire description is unnecessary to inform one skilled in the art of the interchangeability of the catheter species. Therefore, with regard to the detailed description, it is intended to apply to equivalent bitumen devices as well.

The distal portion of the catheter is provided with a stent-retaining sleeve member **36** which has a closed end **35** and an open end **37** and which surrounds the secondary tube **26** and is co-axially slidable therealong. The stent-retaining sleeve **36** is provided with a resilient seal means **38** which provides a liquid or fluid-tight seal between the sleeve **36** and the primary or guidewire tube **22**. The seal means **38** is

relatively stationary with respect to the tube 22, but slidable within the sleeve 36. The sleeve member 36 is further provided with a sliding seal at 40 which is adapted to slide along the outer surface of the secondary tube 28 with the tubular sleeve 36, but remains relatively stationary with respect to the sleeve 36 and provides a fluid-tight seal between the sleeve 36 and the secondary catheter tube 28. In this manner, the pressure seals 38 and 40 provide an extendable fluid-tight chamber 42 between the sleeve 36 and the catheter system such that pressurized fluids expelled from the distal end 44 of the secondary tube lumen 26, which preferably occurs between seals 38 and 40, will produce the desired retraction of the sleeve 36. The device also contains spaced proximal and distal radiopaque markers 46 and 48 and a stent 50 is shown assembled in the delivery or reduced diameter position. A soft distal nose or guiding cap attached to the main or primary catheter tube is shown at 52.

FIGS. 2 and 3 further illustrate the operation of the deployment arrangement of FIG. 1. In FIG. 2, the sleeve element 36 is pictured as having advanced relative to the stent in a proximal direction about as far as the location of the distal end of the stent 50 which is constrained axially between the stationary seal 38 and the radiopaque member 48. The radiopaque member 48 may be used to locate or mark the distal end of the stent fluoroscopically. In FIG. 3, the sleeve element 36 is advanced an additional distance allowing the distal end of the stent element 50 to begin to expand radially at the same time in the lumen of interest. Once the sleeve reaches the fully retracted position, the stent is fully expanded and the guiding nose member 52 can be retracted or withdrawn through the expanded stent and the catheter removed in a conventional manner. In this embodiment, when the fluid pressure is removed from the system upon deployment of the stent, the sleeve remains as it was at the end of the deployment function as the catheter is withdrawn.

FIG. 4 depicts an alternative embodiment to that illustrated in FIGS. 1–3 in which the sleeve element 60 is mounted slightly more proximal the distal soft nose or guiding cap 52 and is flanked by a fixed proximal end taper 62 adjacent the open sleeve end 63 and distal closed end with integral sealing taper 64. A sliding seal means 66, similar to seal 40 in FIGS. 1–3, seals the distal end of the sleeve 60 about the periphery of the outer or secondary catheter tube 28. A stationary seal, similar to seal 38 in FIGS. 1–3, is provided at 68 which, with the seal 66, defines a pressurizable internal sleeve volume 70 into which pressurized fluid, normally saline solution, is infused from the lumen 26 via one or more pressure ports as at 72 located just distal the stationary seal 68. The location of the distal end of the catheter system is easily identified by radiopaque marker band 74 and the location of the exterior sliding sleeve 60 and, particularly a stent 76 within the sleeve is defined by additional flanking radiopaque marker bands 78 and 80, respectively.

The arrow indicates the direction of movement of the sleeve which operates in the same manner as the sleeve pictured in the embodiment of FIGS. 1–3. Thus, pressurized fluid infused through the lumen 26 outside the primary catheter tube 22 is infused through the pressure port or ports 72 into the volume 70 where it extends the volume forcing the sleeve 60 to move in a distal direction thereby exposing and allowing the expansion of the compressed or contained stent member 76 such that the proximal portion at 82 is the first to be released and expand with the remainder following thereafter. In this manner, precise placement or location of the proximal end of the stent may be used to define the final implant location.

A different embodiment of a sleeve system for the stent delivery and deployment system of FIG. 1 is shown in FIGS. 5–7 in which a sleeve member 90 is mounted in a manner similar to sleeve 36 of FIG. 1 at the distal end of the catheter system on the outer or secondary tubular member 28 including peripheral integral slidable proximal sealed end taper 92 sealed by 93 and a pair of radiopaque marker bands 94 and 96 flanking constrained stent member 98 poised for distal first delivery of end 100 first. In this embodiment, however, the dual seal extendable hydraulic volume or cylinder concept of the embodiments at FIGS. 1–4 has been replaced with a normally, collapsed, extending bellows 102 operable between the integral sleeve taper 92 and a sealed stop located at the position of radiopaque marker 94. The term "bellows", as used herein, means an inflatable device that collapses on itself when deflated, but which elongates when filled with fluid. It is exemplified, but not limited to, a pleated fluid bag structure. One or more fluid ports similar to that shown at 72 in FIG. 4 is provided between the bellows 102 and the lumen 26 and the ends 104 and 106 of the bellows 102 form seals against the outer tube 28. The integral seal 93 is adapted to slide proximately upon the extension of the bellows as shown in FIGS. 6 and 7 which illustrate distal deployment of the stent 98 with end 100 expanding initially.

It should be noted in the case of the bellows-operated system that the bellows device itself may be designed to return to a collapsed position as illustrated in FIG. 5 when it is not pressurized. Thus, after deployment of the stent, the pressurized fluid can thereafter be drained from the system and the bellows allowed to collapse or retract on its own, thereby again closing the system for withdrawal through the vascular system of the patient. This feature makes it somewhat easier to withdraw the catheter inasmuch as the gap between the cap 52 and sleeve 90 is again covered. It further allows recapture of a partially deployed stent should positional adjustment be required.

FIG. 8 depicts a system similar to that of FIG. 4 for a bellows-operated system for proximal stent deployment. It includes a sleeve 110 with integral distal end taper seal 112 and matching stationary proximal end taper 114. Radiopaque markers 116 and 118 flank a constrained stent 120 and a further distal marker is shown at 122 close to the catheter guide tip 52. In this embodiment, operation of the bellows is the same as for the embodiment of FIGS. 5–7 with extension of the bellows causing the sleeve 110 to move in a distal direction thereby releasing the proximal end 124 of the stent 120 initially.

FIG. 9 illustrates the catheter equipped with an oppositely disposed pair of bellows-operated sleeve members 130 and 132 having integral oppositely disposed moveable integral end tapers 134 and 136, respectively. The sleeves 130 and 132 are respectively operated by a pair of oppositely disposed extendable bellows 138 and 140 supplied with pressurized fluid from the lumen 26 of outer tube 28 in the manner as previously described such that pressurization by fluid in the lumen 26 simultaneously pressurizes bellows 138 and 140 thereby causing concerted retraction of the sleeves 130 and 132 initially exposing a central portion of the stent 142 contained therein. Radiopaque guide markers are again provided at 144, 146 and 148. As with the other bellows-operated embodiments, relaxation of the fluid pressure in the bellows allows both bellows 138 and 140 to again collapse or retract and return the sleeves to their closed or delivery position for withdrawal of the catheter from the vascular system of the patient upon completion of implantation of the stent 142.

The materials of construction for the catheter and sleeves can be any of those conventionally employed for vascular catheter devices, or the like, including various hydrophilic, generally lubricious bio-compatible materials such as polyimides, or materials capable of being coated with hydrophilic coatings such as polyethylene or polypropylene. In addition, various nylons, urethanes and other materials may be used. The sleeve seals may be of any compatible, resilient material such as a polysiloxane rubber material.

A Further with regard to the fluid supply system, it should be noted that in accordance with the invention, any suitable and compatible fluid infusion device can be employed to introduce fluid into or withdraw fluid from the port **34**. One such device is a syringe-type device known as the NAMIC 13 BREEZE available from Namic Inc., Glen Falls, N.Y. The deployment system of the invention may be designed to operate at relatively elevated pressures and fluid pressures above 10 atmospheres and typically between about 14 and 25 atmospheres are generally employed.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as required. However, it is to be understood that the invention could be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment details and operating procedures, can be accomplished without departing from the scope of the invention itself.

What is claimed is:

1. A delivery system for implanting an expandable stent in a bodily lumen of interest comprising:

(a) an elongate flexible catheter having distal and proximal ends;

(b) at least one moveable fluid-operated, generally cylindrical tubular sleeve for placement over and retention of a stent in a delivery configuration prior to release, said sleeve being axially adjustable relative to said catheter and said stent, and having a closed end and an open end for release of a contained stent;

(c) an expandable stent having a proximal and distal end and being collapsible about said catheter to a delivery configuration of reduced diameter along the length thereof;

(d) a fluid driven hollow bellows mechanism for axially moving said sleeve comprising a bellows having a fixed seal and a moveable seal, said moveable seal being axially moveable by the extension of said bellows with the movement of said sleeve; and

(e) a fluid supply system for supplying fluid to extend said bellows mechanism to operate said sleeve.

2. The apparatus of claim **1** wherein said bellows is self-collapsing.

3. The apparatus of claim **1** wherein said catheter includes inner and outer co-axial tube members describing inner and outer co-axial lumens and including a system for infusing fluid in said outer lumen outside said inner tube member and wherein said bellows is sealed to said outer tube such that infusion ports in said outer tube are in fluid connection with said bellows.

4. The apparatus of claim **1** wherein said catheter has an outer surface and is provided with side-by-side guidewire and fluid lumens, said fluid lumen containing one or more infusion ports for conducting fluid into and out of said bellows and wherein said bellows is sealed to said outer surface of said catheter.

5. The apparatus of claim **1** wherein said open end of said sleeve is the distal end of said sleeve.

6. The apparatus of claim **1** wherein the open end of said sleeve is the proximal end of said sleeve.

7. A method of deploying an expandable stent in a body lumen of interest for procuring implantation of the stent comprising the steps of:

(a) Providing a delivery system for implanting an expandable stent in a body lumen of interest comprising:

(1) an elongate flexible catheter having distal and proximal ends;

(2) at least one moveable fluid-operated, generally cylindrical tubular sleeve for placement over and retention of a stent in a delivery configuration prior to release, said sleeve being axially adjustable relative to said catheter and said stent;

(3) an expandable stent having a proximal and distal end and being collapsible about said catheter to a delivery configuration of reduced diameter along the length thereof;

(4) a fluid driven bellows mechanism for axially moving said sleeve comprising a bellows having a fixed seal and a moveable seal, said moveable seal being axially moveable by said bellows with the movement of said sleeve; and

(5) a fluid supply system for supplying fluid to said bellows mechanism to operate said sleeve;

(b) intraluminally navigating said catheter to place said stent at a deployment site of interest; and

(c) infusing fluid into said bellows mechanism in said sleeve to retract said sleeve axially in a direction to release said stent in situ.

8. The method of claim **7** including the step of reversing the direction of axial movement of said sleeve to recapture said stent prior to the full deployment thereof.

9. The method of claim **8** wherein maid bellows is self-collapsing and further comprising the step of reversing the direction of axial movement of said sleeve by allowing said bellows to collapse.

10. The method of claim **7** wherein said bellows is self-collapsing and further comprising the step of reversing the direction of axial movement of said sleeve returning it to its former position after deployment of said stent by allowing said bellows to collapse.

11. The method of claim **10** further comprising the step of reversing step (b) to withdraw said catheter after the axial movement of said sleeve is reversed.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,817,101
DATED : October 6, 1998
INVENTOR(S) : Gary R. Fiedler

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

In column 8, claim 9, line 45, delete "maid" and insert -- said --.

Signed and Sealed this

Ninth Day of March, 1999

Attest:

Q. TODD DICKINSON

Attesting Officer

Acting Commissioner of Patents and Trademarks